OLDER ADULTS WITH DIABETES AND CANCER: IMPACT ON DIABETES SELF-MANAGEMENT

By

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ABSTRACT

OLDER ADULTS WITH DIABETES AND CANCER: IMPACT ON DIABETES SELF-MANAGEMENT

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Background: Self-management is an important component of diabetes and cancer care. Eight to 18% of individuals with cancer will have preexisting diabetes. Individuals with diabetes who develop cancer have higher mortality and morbidity rates when compared to those without diabetes. **Framework:** This study was guided by the framework for heart failure self-management and family variables by Dunbar et al (2008). **Aims:** The primary aim of this study was to examine the relationship between individual, clinical and behavioral characteristics in adults 50 and older who have preexisting diabetes and are receiving chemotherapy for a solid tumor cancer at baseline and after a minimum of 8 weeks of chemotherapy. A secondary aim for this study was to identify challenges or issues related to diabetes self-management in adults who are undergoing chemotherapy. **Methods:** This pilot study utilized a baseline self-administered survey and a follow up phone survey 8 weeks later. The Diabetes Complications Index, Katz Comorbidity scale, Confidence in Diabetes Scale, outcome expectancies subscale of the Multi-Diabetes Questionnaire and the Hospital Anxiety and Depression Scale were utilized at baseline, in addition to other descriptive questions. The Symptoms of Illness Checklist and Self-care Inventory were utilized at both baseline and 8 weeks to assess symptom severity and diabetes self-management behaviors. The 8 week survey included two open-ended questions that asked patients about challenges or issues with their diabetes self-management, which were tape recorded and then transcribed for analysis. Correlations and a linear regression model were performed for both the baseline and 8 week time intervals to determine factors which influenced

diabetes self-management. A paired t-test was utilized to compare diabetes self-management at baseline and 8weeks to determine if there was a difference in the level of performance. **Sample:** The sample consisted of 34 adults 50 and older with pre-existing diabetes who were receiving chemotherapy for a solid tumor cancer or lymphoma. Individuals were recruited from 8 different community cancer centers in Michigan and Ohio. **Results:** Age, years with diabetes and level of diabetes self-efficacy where all positively correlated with performance of diabetes self-management behaviors at baseline. Age and level of diabetes self-efficacy are significant ($p<.05$) predictors for baseline self-management. At 8 weeks, years with diabetes, level of diabetes severity and diabetes self-efficacy were found to be positively correlated with diabetes self-management behaviors. Diabetes severity, number of comorbidities, ethnicity and baseline self management were noted to be significant ($p<.05$) predictors. A paired t- test indicated significant difference between baseline and 8 week self-management, with individuals having lower scores, indicating they performed less self-management after a minimum of 8 weeks of chemotherapy, with significant ($p<.05$) differences for the specific behaviors of diet and exercise. Themes Identified were: prioritization, health issues and self-management issues. **Implications:** Implications for practice include increasing awareness among nurses and health care providers who care for this population regarding the challenges and issues of managing 2 competing chronic conditions, and the need for increased patient education regarding the management of diabetes while undergoing chemotherapy. Further research needs to look at the relationship between glycemic control, diabetes self-management and health related outcomes in this population. Development of guidelines and quality indicators for patients with diabetes and cancer need to be developed, which improve health related outcomes, survivorship and overall health related quality of life for this population.

This dissertation is dedicated to my husband and best friend
Scott Hershey, for all of his support, patience's, and encouragement in helping
me to achieve my goal.

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Chapter 1

Background and Significance

Diabetes and Cancer are two of the most prevalent diseases in adults 65 years of age and older (Cohen, 2007; Jack, Airhihenbuwa, Namageyo-Funa, Owens, & Vinicor, 2004; Leak, Davis, Houchin, & Mabrey, 2009). An estimated 1.4 million individuals in the U.S. will be diagnosed with cancer this year (Leak, et al., 2009), and 63% of all newly diagnosed cancers will be in individuals 65 or older ("JAHF 2006 Annual Report," 2006). One in 5 adults over 65 have some form of diabetes (Jack, et al., 2004). Diabetes occurs in 8 – 18% of individuals with cancer (Leak, et al., 2009; Psarakis, 2006; Visovsky, Meyer, Roller, & Poppas, 2008).

Self-management is an important component of disease management programs for both cancer and diabetes (Fu, LeMone, & McDaniel, 2004; Gallagher, Donoghue, Chenoweth, & Stein-Parbury, 2008; Sousa, Hartman, Miller, & Carroll, 2009). The dual self-management of cancer and diabetes will be required for many of these individuals. The majority of self-management studies focus on the issues or barriers to self-management related to a single chronic illness (Bayliss, Steiner, Fernald, Carne, & Main, 2003) . Few studies address the issue of self-management in individuals with multiple morbidities (Kerr et al., 2007). The number of comorbidities an individual has is identified as a barrier to effective self-management (Bayliss, Ellis, & Steiner, 2007; Kerr, et al., 2007; Nagelkerk, Reick, & Meengs, 2006). Studies exploring the impact or relationship cancer has on the performance of self-management behaviors for another, were not found.

Individuals with diabetes and cancer may experience competing demands related to symptoms, self-care requirements and effects of treatment which can impact their overall self-management of one or both disorders. Individuals with more than one chronic illness may prioritize one chronic condition over the other, or the symptoms of one disorder may impact the

actual performance of self-management behaviors required for another disorder (Kerr, et al., 2007; Krein, Heisler, Piette, Makki, & Kerr, 2005). Competing demands for chronic disease self-management are considered the rivalry between the self-management requirements of two or more chronic health conditions, as well as the individual, behavioral and clinical characteristics specific to the individual. Competing demands may develop from symptoms and care requirements associated with cancer and its treatment and impact the actual performance of required self-management activities for diabetes. Overall self-management has been noted to be poorer in individuals with comorbid chronic pain and depression (Gonzalez et al., 2007; Krein, et al., 2005; Lee et al., 2009). Based on the literature, it can be hypothesized that cancer and its treatment may have a negative impact on diabetes self-management in older adults with diabetes who are undergoing chemotherapy for the treatment of cancer.

The main purpose of this exploratory study is to examine the relationship between individual, clinical, and behavioral characteristics and the performance of diabetes self-management behaviors in older adults receiving outpatient chemotherapy for cancer. The secondary purpose of this study is to identify common issues or concerns related to being able to continue self-management of diabetes which may contribute to the development of competing demands in older adults undergoing chemotherapy for cancer. The following sections will further explore the concept of self-management and the impact cancer may have on the self-management of diabetes.

Self-Management of Chronic Disease

The importance of self-management of chronic disease was highlighted in the Institute of Medicines report, *Crossing the Quality Chasm* (2001). This report cited self-management as one of the essential components of chronic disease management programs (*Crossing the quality*

chasm: A new health system for the 21st century, 2001). Older adults with comorbidities will participate in some type of self-management activity to manage their chronic conditions (Gallagher, et al., 2008). Most older adults with a chronic illness will need to make decisions regarding their diet, level and type of exercise, and following prescribed medication regimens. For the older adult with a chronic illness, self-management is essential for maintaining functional ability, prevent complications, and to slow or prevent progression of the disorder. The participation in self-management activities for chronic disease by older adults has been shown to alleviate symptoms, and improve physical and mental health outcomes (Harvey et al., 2008).

Diabetes Treatment and Self-Management

Self-management activities for individuals with diabetes includes the monitoring of blood sugars, regular foot exams and the adjustment of medications based on their blood sugars (Bodenheimer, Lorig, & Holman, 2002; Funnell, 2008). Older adults with diabetes will usually need to monitor their blood sugars, administer insulin and/or take oral medications, monitor their diet and follow an exercise program to assist in the management of and prevent complications associated with diabetes (Funnell, 2008). Older adults with diabetes need to monitor symptoms which could be caused by elevated or low glycemic levels. Dose adjustment of insulin may be required in order to manage glycemic levels. Diet and exercise programs may also need to be adjusted in order to maintain glycemic control. Daily foot inspections and regular eye exams are also an essential component of the diabetic's self-management plan. The individual with diabetes will need to perform multiple different self-management activities in order to manage their diabetes at home.

The performance of self-management activities for diabetes has been shown to improve glycemic control and decrease complications associated with the disease (Heisler, Piette,

Spencer, Keiffer, & Vijan, 2005; Lee, et al., 2009; Whittemore, Melkus, & Grey, 2005). A lack of attention to diabetes self-management in individuals with cancer can impact overall glycemic control and increase the risk of infection and other complications associated with cancer and/or diabetes (Psarakis, 2006). This possible lack of attention may be due to cancer related symptoms, other individual, clinical or behavioral characteristics or self-management requirements for cancer. The following section will explore cancer treatment and self-management.

Cancer Treatment and Self-Management

Solid tumor cancers, i.e. breast, lung colon etc, and lymphomas comprise the majority of all diagnosed cancers in the U.S. ("Cancer Facts and Figures," 2009). Patients with cancer may undergo multiple treatment modalities, including surgery, radiotherapy, chemotherapy and/or endocrine therapy (Tadman & Roberts, 2007). Each type of treatment is done either in conjunction with another or individually over different time frames (Tadman & Roberts, 2007). Dosing used for each of these modalities is dependent upon the cancer being treated (Tadman & Roberts, 2007).

Chemotherapy is one of the most common forms of cancer treatment used today, and is considered to be safe and effective in older adults (Green & Hacker, 2004). Frequency and strength of dosing are dependent upon type of and stage of cancer, age of the patients, as well as the presence of comorbidities (Tadman & Roberts, 2007). The duration of treatment is also dependent on type of cancer and type of chemotherapy being used; many patients may receive chemotherapy for a minimum of 3 – 6 months or longer (Tadman & Roberts, 2007). This extended duration of treatment and the normal physiologic changes associated with aging may impact how the older adult tolerates chemotherapy treatments and their tolerability to the side-

effects associated with chemotherapy (Green & Hacker, 2004). The associated symptoms, such as fatigue, nausea and loss of appetite which occur with chemotherapy, may have an impact on an individual's ability to continue to self-manage an existing chronic condition, such as diabetes.

Common symptoms experienced in older adults undergoing chemotherapy are pain, fatigue, depression, nausea and vomiting, and loss of appetite. These symptoms in older cancer patients are usually overlapping (Rao & Cohen, 2004). The presence of comorbidities in older adults with cancer can increase the severity and number of symptoms experienced and decrease level of physical functioning (Reiner & Lacasse, 2006). The symptoms experienced by older adults with cancer who are receiving chemotherapy have been shown to impact their activities of daily living (Reiner & Lacasse, 2006). Older cancer patients with more advanced disease and comorbidities have an increased risk for poorer physical function, higher levels of depression, lower quality of life and a higher risk of death (Deimling, Bowman, & Wagner, 2007; Heidrich, Egan, Hengudomsub, & Radolph, 2006; Mystakidou et al., 2006; Reiner & Lacasse, 2006).

Self-management is one of the key strategies utilized by cancer patients to manage their cancer and cancer treatment related symptoms (Fu, et al., 2004). Over the past few years the role of the patient in relation to their cancer care has changed (Tadman & Roberts, 2007). Patients are encouraged to manage their lives, deal with their treatment processes and manage outcomes associated with this treatment (Tadman & Roberts, 2007). Decreased physical function and depression, in addition to the symptom burden experienced have all been noted to be barriers to self-management by adults with multi-morbidities (Bayliss, Ellis, et al., 2007; Bayliss, et al., 2003). The associated symptoms which occur with chemotherapy may have an impact on an individual's ability to continue to self-manage an existing chronic condition, such as diabetes.

The following section will explore the relationship between cancer and diabetes self-management.

Cancer and Diabetes Self-Management

The literature on cancer has shown the impact chemotherapy can have on an individual of any age. Chemotherapy is associated with an increase in symptoms such as pain and fatigue, increased risk for infection and altered nutritional status (Tadman & Roberts, 2007). Older adults with comorbidities such as diabetes and cancer are more likely to experience fatigue, weakness, impaired movement and functioning and have an increased risk for falls (Green & Hacker, 2004). As the population ages, the prevalence of the co-existence of cancer and diabetes will become more common (Smyth & Smyth, 2005). Individuals with diabetes are at increased risk for developing cancer (Attili et al., 2007; Extermann, 2007) and increased mortality after developing cancer than those without diabetes (Attili, et al., 2007).

Individuals with diabetes and cancer are at increased risk of having poorer outcomes when compared to individuals with cancer only (Psarakis, 2006). The presence of cancer and its associated treatment may negatively influence outcomes associated with the treatment and self-management of diabetes (Leak, et al., 2009). The effects of chemotherapy may create a competing demand between cancer and diabetes self-management due to the effects of symptoms associated with chemotherapy. The impact from symptoms such as fatigue, pain, loss of appetite, nausea and vomiting may affect an individual's ability to continue to perform self-management activities for their diabetes. The increase in symptoms associated with chemotherapy and a decline in physical function may impact the ability to exercise and the ability to perform tasks such as blood glucose monitoring (Leak, et al., 2009; Psarakis, 2006).

Older adults with diabetes who are undergoing chemotherapy for cancer may experience increased symptoms, and decline in physical function (Green & Hacker, 2004; Psarakis, 2006). The older adult with cancer may experience the competing effects of symptoms related to cancer or it treatment with existing comorbidities (Kerr, et al., 2007; Terret, Zulian, Naiem, & Albrand, 2007; Zeber et al., 2008). Cancer patients experience a myriad of symptoms which may impact their ability to continue to perform self-management activities for existing chronic conditions such as diabetes (Jerant, von Friederichs-Fitzwater, & Moore, 2005; Terret, et al., 2007).

The impact cancer and treatment with chemotherapy has on the older adult's ability to self-manage existing chronic conditions such as diabetes is unknown. Certain chemotherapy regimens can lead to hyperglycemia and the development of symptoms such as nausea, vomiting, and fatigue. These symptoms may influence diet and exercise regimens impacting glycemic control (Psarakis, 2006). Individuals may have difficulty in being able to follow diet and exercise plans due to symptoms associated with their cancer and its treatment and decide to no longer perform self-management activities. Individuals may also find it more difficult to manage their blood sugars due to effects of treatment causing hyperglycemic or hypoglycemic episodes.

The symptom burden experienced by individuals undergoing treatment for cancer may produce levels of fatigue and pain which interferes with ability to exercise, glucose monitoring, taking medications as prescribed and following an appropriate diet. Symptom burden associated with cancer related fatigue has been noted to impact physical functioning and ability to perform activities of daily living (Hofman, Ryan, Figueroa-Moseley, Jean-Pierre, & Morrow, 2007). Self-management activities associated with administering medications was negatively impacted in individuals receiving radiotherapy, due to the symptom distress they experienced (Oberst, Hughes, Chang, & McCubbin, 1991). One can conclude that symptoms associated with

chemotherapy would have a negative impact on the continued performance of self-management activities in individuals with cancer and diabetes who are undergoing chemotherapy.

Older adults have to be able to self-manage their cancer and a preexisting comorbidity such as diabetes while undergoing chemotherapy; they may experience changes or perceive changes in their health status, mood and number of symptoms they experience on a daily basis (Psarakis, 2006; Reiner & Lacasse, 2006). The changes in overall health status experienced by individuals with cancer and diabetes may cause them to change how they self-manage their diabetes. The individual with diabetes and cancer will need to perform additional self-management activities related to their cancer and its treatment. The self-management of cancer related symptoms may be prioritized over taking care of and performing self-management activities for diabetes (Kerr, et al., 2007). Lack of attention to diabetes self-management can impact overall glycemic control. Individuals with poorer glycemic control, which results in higher blood glucose levels, are at increased risk for infection and other complications associated with cancer and/or diabetes (Leak, et al., 2009; Psarakis, 2006). It is unknown how diabetes self-management is impacted by cancer related symptoms and individual, clinical or behavioral characteristics of the individual, and if the competing demands of cancer causes a "lack of attention" to diabetes self-management.

The impact that cancer and its treatment has on an older adult's ability to continue to self-manage their diabetes is not known, specific studies exploring this relationship were not found by this author. The literature suggests diabetes self-management maybe negatively impacted in individuals with cancer undergoing treatment with chemotherapy (Leak, et al., 2009; Psarakis, 2006). One can hypothesize older adult's place less emphasis on self-managing their diabetes due to the symptoms they experience associated with their cancer and cancer treatment. Kerr et

al (2007) noted how much a patient's diabetes self-management is impacted by another condition is dependent upon the burden and severity of the competing disorder. Individuals may prioritize a disorder that is more severe or life-threatening over another which is perceived as less severe (Kerr, et al., 2007; Piette & Kerr, 2006). No studies were found which addressed the impact cancer and its treatment has on the self-management of diabetes. In order to begin to understand how cancer and its treatment impacts an older adults ability to continue to self-manage their diabetes an exploratory study will be developed.

Significance

One of the initiatives of The U.S. Department of Health and Human Services is in regards to individuals who have multiple chronic conditions (MCCs). One of the main focuses of this initiative is to assist individual with MCCs with self-management, in order to reduce the burden of MCC to society and improve the health of individuals with MCCs (Barone et al., 2010). As the population ages the number of individuals with diabetes and cancer will most likely increase. There is a gap in the literature regarding the impact a new chronic condition can have on the self-management of an existing condition such as diabetes. There is also a lack of knowledge regarding the impact cancer and its treatment may have on the self-management of existing chronic conditions in older adults.

Individuals with diabetes who develop cancer are more likely to be admitted to the hospital, develop an infection or die from their cancer (Barone et al., 2008; Srokowski, Fang, Hortobagyi, & Giordano, 2009). A pre-existing diagnosis of diabetes is present in 8 – 18% of individuals who are diagnosed with cancer (Psarakis, 2006). It is unknown why these individuals have higher mortality and complication rates when compared to individuals without diabetes. It has been hypothesized that glycemic levels may play a role in the development of

complications for individuals with diabetes who are undergoing chemotherapy (Attili, et al., 2007). Self-management behaviors positively influence glycemic control in individuals with diabetes (Gold et al., 2008; Hartz et al., 2006; Scain, Friedman, & Gross, 2009). Individuals who perform fewer self-management activities for their diabetes have poorer glycemic control (Hartz, et al., 2006). Poorer glycemic control in individuals with diabetes is also associated with poorer outcomes, increased infection rates and increased morbidity and mortality (Blonde, 2007; Krinsley, 2008; Patel, 2008; Sousa, et al., 2009). Nurses and other healthcare providers need to be aware of the occurrence of potential competing demands for self-management in adults with more than one chronic condition, particularly cancer and diabetes. The impact that cancer and its treatment has on diabetes self-management may influence the glycemic control patients have during this period.

This study seeks to develop a beginning understanding of how self-management for diabetes may be impacted by cancer and its treatment, and how self-management for an existing comorbidity may be impacted by a new chronic illness. In addition, this exploratory study will begin to identify the relationship between factors such as symptoms; self-efficacy and outcome expectancies have on the performance of self-management activities for diabetes in this population. This exploratory study will contribute to the knowledge base regarding the impact cancer has on an older adults ability to continue to successfully self-manage their diabetes while undergoing chemotherapy and identify specific concerns or issues related to diabetes self-management in this population. Results from this study can be used to develop future studies which explore the relationship between self-management of diabetes in individuals with cancer and glycemic control, as well as, the development of nursing interventions to assist in the improvement of overall health related quality of life in this population.

In order to address this gap in knowledge and exploratory study will be developed to explore the relationship between cancer treatment and diabetes self-management. This study will be guided by the following primary and secondary aims:

Study Aims

Primary Aims.

1) Among patients with pre-existing diabetes who are either starting or are currently receiving outpatient chemotherapy for a solid tumor cancer how does clinical characteristics associated with diabetes and cancer and behavioral characteristics relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

2) Among patients with pre-existing diabetes who have completed a minimum of 8 weeks of outpatient chemotherapy, how does baseline clinical and behavioral characteristics, baseline diabetes self-management behaviors and symptom burden after 8 weeks of chemotherapy relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

Secondary Aim.

1) To identify common challenges or concerns regarding the self-management of diabetes in older adults after completing at least 8 weeks of outpatient chemotherapy.

Influence of Individual, Clinical and Behavioral Characteristics on Self-Management

As identified in the aims, the antecedents of clinical and behavioral characteristics, and the co-variate of individual characteristics can have an influence on the performance of self-management behaviors (Dunbar, Clark, Quinn, Gary, & Kaslow, 2008). Previous research related to self-management has identified a positive or negative influence of these characteristics on the actual performance of self-management behaviors (Bayliss, Ellis, et al., 2007; Dunbar, et al., 2008; Gallant, Spitze, & Prohaska, 2007; Nagelkerk, et al., 2006). The following sections will discuss each of these characteristics and their relationship to self-management behaviors.

Individual Characteristics. Age, sex, level of education, marital status, race and

Ethnicity and socio-economic status have all been noted to influence the performance of self-management behaviors for chronic disorders (Jenerette & Phillips, 2006; Jerant, et al., 2005; McDonald-Miszczak & Wister, 2005; Nagelkerk, et al., 2006). The amount of influence age and sex has on the actual performance of self-management activities is unclear (MacInnes, 2008). The effect each of these has may be dependent upon the specific activity required. Women are more likely to follow prescribed medication regimens, where men are more likely to follow prescribed exercise regimens (Burnette, Mui, & Zodikoff, 2004; MacInnes, 2008). Individuals of who are a minority, have lower levels of education, belong to a lower financial bracket, or live alone are more likely to experience more barriers associated with the performance of self-management activities (Bayliss, Ellis, et al., 2007; Bayliss, et al., 2003; Dunbar, et al., 2008; Gallant, et al., 2007; MacInnes, 2008; Nagelkerk, et al., 2006; Tang, Brown, Funnell, & Anderson, 2008).

Clinical Characteristics. The complexity of the disorder, the plan of care, the concordant or discordant nature of comorbidities, and the symptom experience associated with different chronic conditions have all been shown to impact self-management behaviors (Bayliss, Ellis, et al., 2007; Bayliss, et al., 2003; Kerr, et al., 2007; Piette & Kerr, 2006). Difficulty in recognizing and managing symptoms associated with different conditions, is an issue for individuals with more than one comorbidity (MacInnes, 2008). The overall burden of disease is greater in individuals with multiple comorbidities and is considered a barrier for effective self-management of coexisting comorbidities (Bayliss, Ellis, et al., 2007). The longer an individual has a disorder, the more likely they are able to recognize symptoms and use self-management strategies effectively for their existing comorbidity (MacInnes, 2008). Clinical characteristics can influence the actual performance of self-management activities. It is unclear how the

development of a new comorbidity, such as cancer, may impact or influence the actual performance of self-management activities for an existing comorbidity, such as diabetes.

Behavioral characteristics. Factors which influence how one behaves or performs an activity such as self-efficacy, outcome expectancies, and depression/anxiety play an essential role in the performance of self-management behaviors by adults with a chronic condition. Each of these have been found to be correlated with the actual performance of self-management behaviors for a disorder (Bai, Chiou, & Chang, 2009; Conn, 1998; Williams & Bond, 2002). Individuals with lower levels of self-efficacy, higher levels of depression/anxiety or feel that the performance of self-management behaviors will not prevent progression of their disease, or complications associated with their disease, are less likely to perform self-management activities for their comorbidity (Aljasem, Peyrot, Wissow, & Rubin, 2001; Bai, et al., 2009; Chlebowy & Garvin, 2006; Conn, 1998; Hall, Rodin, Vallis, & Perkins, 2009; Luyster, Hughes, & Gunstad, 2009; Williams & Bond, 2002).

The existing literature identified several individual, clinical and behavioral characteristics that can have an influence on the performance of self-management activities for comorbidities. Only a brief picture of how each of these may impact self-management behaviors was presented here. Each of these and their relationship to the performance of self-management behaviors will be explored further in Chapters 2 and 3.

Chapter 2

Conceptual Framework

This exploratory study will be guided by the framework for heart failure self-management and family variables by Dunbar et al (2008), see figure 1. It is important when studying self-management that one considers all factors which can influence the actual performance of self-management behaviors. Literature has shown the actual performance of self-management behaviors can be influenced by individual specific characteristics such as age, disease specific factors such as type of disorder, number of comorbidities and their associated treatment, as well as psychological or behavioral factors such as self-efficacy.

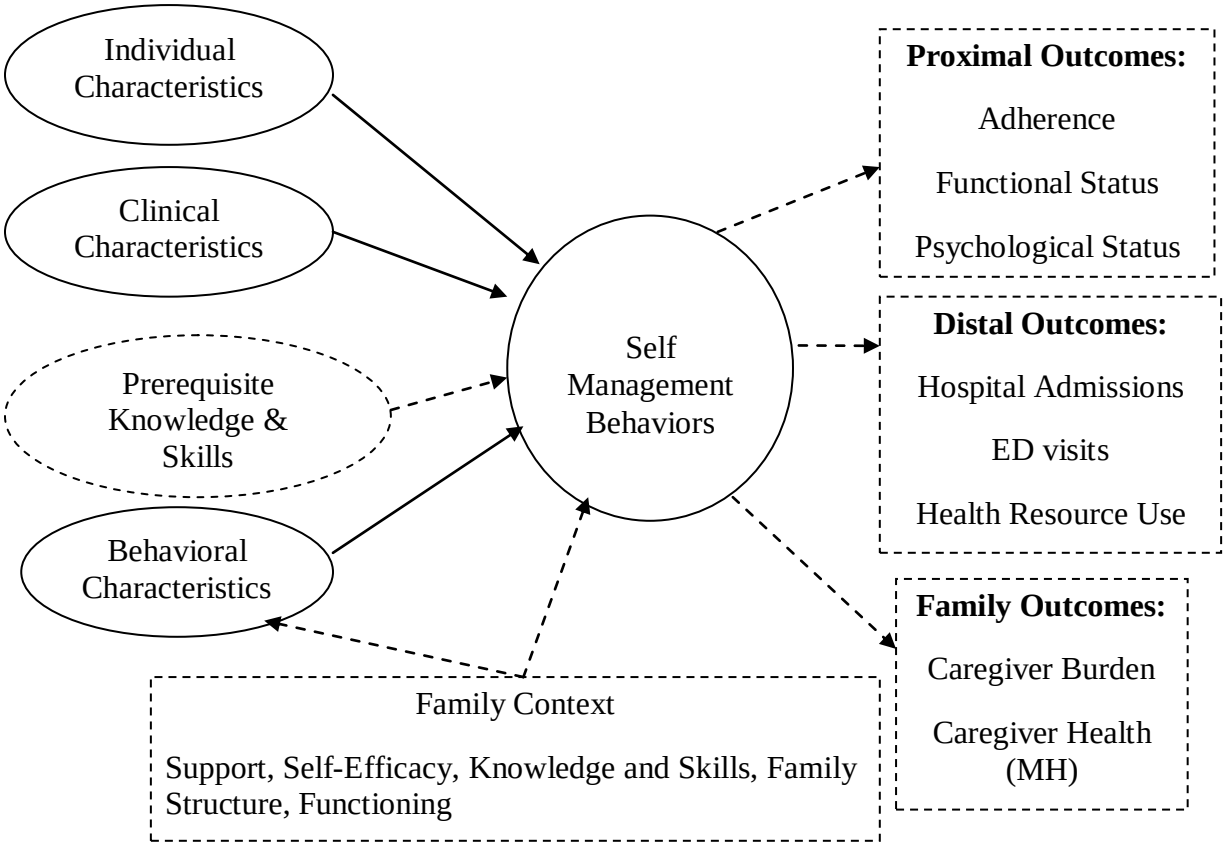

Figure 1: Dunbar et al (2008) Framework for heart failure self-management and family variables. Certain solid lines were changed to broken lines in order to indicate areas and relationships for future research by this investigator. Solid lines indicate relationships being explored in this study.

The Dunbar et al (2008) framework for heart failure self-management with family variables was chosen for this study for it includes the majority of factors which can impact self-management behaviors as well as the outcomes associated with the performance of self-management behaviors. This framework uses a structure-process-outcome format, to identify the antecedents to the processes of self-management behaviors and outcomes of HF self-management, and was developed by Dunbar et al (2008) in order to depict what is currently known in the literature regarding the relationships between antecedents to self-management behaviors and outcome of self-management behaviors.

The framework in addition depicts the influence the family context has on the self-management behaviors of individuals with heart failure (Dunbar, et al., 2008). Dunbar et al (2008) noted family was a strong influencing factor for self-management, since most self-management occurs under the influence of family. The family context includes family support and functioning, efficacy, and the family structure and knowledge and skills (Dunbar, et al., 2008).

Antecedents to self-management behaviors include individual, clinical and behavioral characteristics, prerequisite knowledge and skills and the family context. For the purpose of this study only the antecedents of individual, clinical and behavioral characteristics, as well as the process variable of self-management behaviors will be addressed. The model components omitted from this study will provide a foundation for future work to be developed, based on the results from this study.

Individual characteristics include socio-demographics such as age, sex, and education level. Severity of illness, such as stage or classification of illness, number of comorbidities and plan of care including self-care regimens are part of clinical characteristics. Behavioral

characteristics are considered the individual's ability to attend to behaviors, motivation, self-efficacy, and mood states. These antecedents influence self-management behaviors for heart failure. Outcomes are considered proximal, distal or family related. Proximal outcomes include adherence, functional status, and psychological status. Distal outcomes include hospital admissions, ED visits, health resource use and cost. Caregiver burden and caregiver health make up the family outcomes. All outcomes are influenced by the self-management behaviors of the individual.

As previously mentioned, the framework for heart failure self-management with family variables (Dunbar, et al., 2008) provides the guidance for this study. The following framework based on the Dunbar model, (see Figure 2), will be used to guide this study. The model for this study excludes the antecedent components of prerequisite knowledge and skills, and the family context, as well as the proximal, distal and family outcomes identified in the original model. These components/variables are not being considered for this current exploratory study, will be used as future studies are developed based on the findings of this study.

For the purposes of this study, the framework uses the structural components or antecedents of individual, clinical and behavioral characteristics, which influence the process of self-management behaviors at baseline and at 8 or more weeks of receiving chemotherapy. In this framework the process component of self-management behaviors at baseline is also used as an antecedent to self-management behaviors at 8 weeks or more of chemotherapy. The following sections will further define each of the model components and their relationship to self-management behaviors or changes in self-management behaviors.

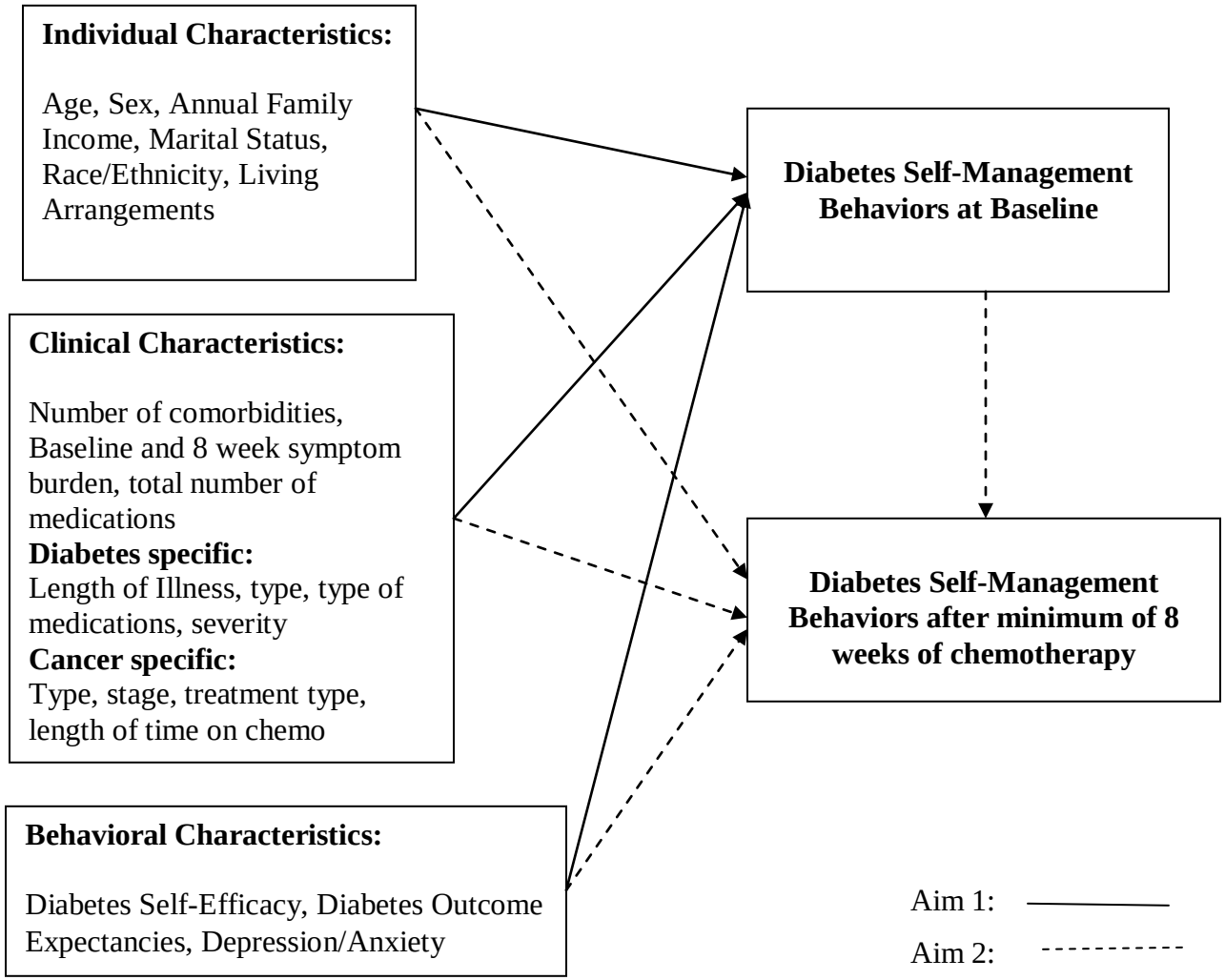

Figure 2: Study framework adapted from the framework for heart failure self-management with family variables by Dunbar et al (2008)

Diabetes Self-Management Behaviors

The outcome component of this model is the performance of diabetes self-management behaviors. Self-management is used as part of many chronic disease plans of care. Diabetes, Chronic Obstructive Pulmonary Disease (COPD) and congestive heart failure (CHF) all require patients to perform some type of self-management regime (Chen, Chen, Lee, Cho, & Weng, 2008; Funnell, 2008; Washburn & Hornberger, 2008). Individuals with Diabetes will need to monitor and maintain their condition in between visits with their health care provider. Individuals with Diabetes will usually have to monitor their blood sugars, administer insulin and/or take oral medications, monitor and follow a diabetes specific diet, and follow an exercise program to assist in the management of and prevent complications related to their diabetes (Funnell, 2008). Proper self-management can improve diabetes outcomes, if individuals are able to sustain the complex array of self-management behaviors required of them (Heisler, Smith, Hayward, Krein, & Kerr, 2003).

Heisler et al (2003) described self-management as a set of skilled behaviors used by patients to sustain complicated medication, diet and exercise regimens. Individuals with Diabetes, who are on insulin, may need to adjust their dose based on their blood sugars, take several medications at different times during the day, and/or take medications based on specific blood glucose levels (Nathan et al., 2006; Ripsin, Kang, & Urban, 2009; Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006). The sustainment of these complicated regimens is part of self-management regimens for many individuals with diabetes (Heisler, Smith, et al., 2003). For individuals with diabetes, monitoring and following a specified diet and regular exercise plan to assist in glycemic control is an important self-management behavior. Diets may need to be adjusted depending on the level of exercise individuals participate in.

Exercise programs for individuals with diabetes include cardiovascular exercises such as walking or jogging, as well as resistance training with weights (Sigal, et al., 2006). The ability to perform and maintain these complicated regimens is not only influenced by an individual's PSE, and individual characteristics, but also their clinical characteristics. Individuals who already have one chronic disease to manage may find it difficult to continue their self-management routine when they develop a second chronic condition, such as cancer, which may be more life threatening, and also require them to perform self-management activities.

Most individuals with cancer who are undergoing chemotherapy will experience symptoms of fatigue, nausea, vomiting, diarrhea and decreased appetite which can impact diet and exercise regimens for the self-management of diabetes (Leak, et al., 2009; McCoubrie, Jeffrey, Paton, & Dawes, 2005; Smyth & Smyth, 2005). Cancer specific medications for managing symptoms and chemotherapy regimens may impact glucose levels. Many cancer treatment protocols will use glucocorticosteroids as part of the treatment regimen which can cause glucose levels to increase (Leak, et al., 2009). This increase in glucose levels may require additional medication management by the patient in order to control. Patients may need to learn additional skills in order to maintain and manage their diabetes, as well as skills to manage their cancer.

The learning and acquiring skills in order to carry on and actively participate in the care of one's chronic disease is considered a component of self-management (Blakeman, Macdonald, Bower, Gately, & Chew-Graham, 2006; Bodenheimer, Lorig, Holman, & Grumback, 2002; Lorig, 1993; Lorig & Homan, 2003). Gallant et al (2008) described self-management as activities undertaken by individuals to control or minimize the impact a disease or condition can have on their physical health status and functioning, and to help them cope with the psychosocial

consequences of living with a chronic illness. Self-management includes the responsibility of being able to interpret the effects of diseases and treatments in order to be able to use medications properly, change behaviors in response to symptom changes, interpret and report symptoms accurately and to adjust to the social and economic consequences of having a chronic illness (Holman & Lorig, 2004). Self-management occurs when individuals engage in activities to control or reduce the impact of their disease, and can be described as a daily routine that is modified by the patients perceived needs, physical abilities and sources of support (Bayliss, Edwards, Steiner, & Main, 2008; Bourbeau, 2008; Grey, Knafl, & McCorkle, 2006). For the purposes of this study self-management behaviors will be considered the activities individuals perform to maintain their diabetes. The performance of the activities which compromise self-management behaviors for diabetes are influenced by the structural or antecedent components of the framework. These relationships will be explored in the following sections.

Individual Characteristics

The structural component of individual characteristics comprises the variables of age, sex, marital status, race/ethnicity, living arrangements, financial and educational levels. Each of these individual characteristics may play a role in regards to the performance and/or the continued performance of self-management behaviors (Bayliss et al., 2007; Bayliss, et al., 2003; Dunbar, et al., 2008; MacInnes, 2008). The performance of self-management behaviors tend to increase as an individual ages (Grey, et al., 2006; MacInnes, 2008). Individuals who are considered elderly or frail may perform self-management behaviors less, and be more dependent upon spouses or caregivers to provide or assist with recommended self-management behaviors (Brewer-Lowry, Arcury, Bell, & Quandt, 2010; Grey, et al., 2006). Women are more likely to ensure that a spouse or partner is adherent and performing recommended self-care activities vs.

performing them themselves (Grey, et al., 2006). The nature or amount of self-management behaviors performed may also vary by other demographic variables such as race, educational and income levels (Dunbar, et al., 2008; Grey, et al., 2006).

Each of these socio-demographic variables which make up individual characteristics can have a positive or negative influence on the performance of recommended self-management behaviors. The role each of these variables has on the continued performance of self-management behaviors for one disorder, when they are faced with the management of a new disorder is unclear. Based on the known positive or negative impact each of these can have on the performance of self-management behaviors, it is essential that they be considered when looking at the effect one condition may have on the performance of self-management behaviors for another. For the purposes of this study individual characteristics are considered the socio-demographic variables which can either have a positive or negative influence on the performance of self-management behaviors for diabetes in individuals undergoing treatment for cancer.

Clinical Characteristics

Clinical characteristics are those variables that are associated with the individuals general health and specific health conditions. General health variables include the number of comorbidities or chronic conditions an individual has and the symptoms they experience associated with these conditions. Specific health conditions, for this study, include diabetes and cancer. Diabetes specific variables include length of illness, diabetes type, number of diabetes related medications, and diabetes severity. Cancer specific variables include type, stage, number of cancer related medications, chemotherapy treatment regimen and length of time the individual has been on chemotherapy.

Clinical characteristics have been noted to influence the performance of self-management behaviors either positively or negatively (Aljasem, et al., 2001; Janz et al., 2007; Kerr, et al., 2007; Mann, Ponieman, Leventhal, & Halm, 2009; Molasiottis, Stricker, Eaby, Velders, & Coventry, 2008; Rao & Cohen, 2004). The longer an individual has a chronic condition, such as diabetes, the more likely they are to perform self-management behaviors (MacInnes, 2008). The more symptoms an individual experiences and the overlapping or competing effects of these symptoms with required self-management behaviors can negatively impact their performance (Cleeland et al., 2000; Hofman, et al., 2007; Kerr, et al., 2007; Oberst, et al., 1991; Reiner & Lacasse, 2006). The greater the number of medications an individual takes, the more complex their treatment plan and the severity of their illness can also have a negative impact on the performance of self-management behaviors (Bayliss, Ellis, et al., 2007; Mann, Ponieman, Leventhal, & Halm, 2009; Piette & Kerr, 2006).

In summary, clinical characteristics are those variables which are associated with an individual's health or disease state. These variables in general have been shown to negatively impact the performance of self-management behaviors, with the exception of length of time the individual has had the condition. The amount of influence these variables have on the actual performance of self-management behaviors maybe influenced by certain behavioral characteristics, these will be explored in the following section.

Behavioral Characteristics

Behavioral characteristics are factors which influence how one may react to, manage a specific problem, and their confidence to do so. Motivation, mood states, ability and self-efficacy (SE) have all been identified as behavioral characteristics which influence self-management behaviors (Dunbar, et al., 2008). For the purposes of this study perceived Diabetes

self-efficacy (PDSE), outcome expectancies (OE), depression and anxiety will be utilized to explore the relationship to the performance of self-management behaviors for diabetes in adults undergoing chemotherapy.

Higher levels of depression and anxiety, lower levels of SE and/or OE, have been shown to negatively impact the performance of self-management behaviors (Aikens, Perkins, Piette, & Lipton, 2008; Aljasem, et al., 2001; Chlebowy & Garvin, 2006; Egede, Ellis, & Grubaugh, 2009; Williams & Bond, 2002). Individuals who have higher levels of self-efficacy and feel like they can have a positive impact on their outcomes are more likely to perform required self-management behaviors (Aljasem, et al., 2001; Chlebowy & Garvin, 2006). Individuals who have higher levels of self-efficacy and feel they have some control over their outcomes, exhibit higher levels of confidence and feel they are able to carry out the required behaviors (Aljasem, et al., 2001; Sousa, et al., 2009).

In summary, behavioral characteristics are factors associated with ones mood, confidence and beliefs about being able to carry out a particular activity and that the impact the performance of a particular activity will have on their overall health state. Behavioral characteristics can have a negative or positive influence on the performance of self-management behaviors for diabetes, dependent on their level. It is not clear how these variables will impact the performance of self-management behaviors after being on chemotherapy for 8 weeks or more. It can be hypothesized that individuals who have higher levels of SE and OE, and lower levels of depression and anxiety at baseline, will be more likely to continue to perform self-management behaviors for their diabetes.

The framework for this study uses components of the framework for heart failure self-management and family variables by Dunbar et al (2008) to identify how self-management

behaviors may be impacted in older adults with diabetes while undergoing treatment for cancer. In the framework for this study the individual, clinical and behavioral characteristics have a positive or negative influence on the performance of self-management behaviors for diabetes at baseline and after being on chemotherapy for at least 8 weeks. By understanding the relationship between clinical, behavioral and individual characteristics and the performance of self-management behaviors for diabetes in individuals undergoing treatment for cancer can help clinicians caring for this population, in order to improve health related quality of life outcomes. What is known in regards to self-management of diabetes, and the factors which may influence this will be further explored in Chapter 3.

Chapter 3

Integrated Review of the Literature

In 1998, Wagner published a model of improvement of chronic illness care, which is known as the Chronic Care Model. One of the main constructs of this model is self-management support (Wagner, 1998). The importance of self-management was also highlighted in the Institute of Medicine's report, *Crossing the Quality Chasm (Crossing the quality chasm: A new health system for the 21st century, 2001)*. This reported cited self-management as one of the essential components of chronic disease management programs, in order for patients and their families to be able to acquire skills needed to make lifestyle changes. Over the past several years the concept of self-management of comorbidities or chronic disease, such as diabetes mellitus (DM), congestive heart failure (CHF) and arthritis, has been the focus of multiple research studies (Albert, Buchsbaum, & Li, 2007; Aljasem, et al., 2001; Atak, Tanju, & Kose, 2008; Chen & Wang, 2007; Chriss, Sheposh, Carlson, & Riegel, 2004; Jerant, et al., 2005; McDonald-Miszczak & Wister, 2005; Nagelkerk, et al., 2006).

Self-management of symptoms has also been the focus of cancer studies investigating how individuals manage their cancer and cancer treatment related symptoms (Borthwick, Knowles, McNamara, O'Dea, & Stroner, 2003; Chou, Dodd, Abrams, & Padilla, 2007; Hoffman et al., 2009; Magnan, 2004; Miaskowski et al., 2004; Williams et al., 2006; Wydra, 2001). More recently researchers have started to investigate the impact of multiple comorbidities has on an individuals ability to self-manage their chronic conditions (Bayliss, Edwards, Steiner, & Main, 2008; Bayliss, Ellis, et al., 2007; Bayliss, et al., 2003; Borg, Ingalill, & Blomqvist, 2006; Kerr, et al., 2007; Schoenberg, Leach, & Edwards, 2009). This literature does not specifically address the impact that one comorbidity may have on the self-management of another, such has the impact cancer has on diabetes self-management. Self-management is an essential part of chronic

disease management and individuals with multiple morbidities need to be able to juggle managing both conditions in order to achieve desirable outcomes for all of their conditions, and maintain their overall quality of life (Bayliss, Bosworth, et al., 2007; Bayliss, Ellis, et al., 2007).

Over the past few years the relationship between cancer and diabetes has been the topic of only a few published articles (Leak, et al., 2009; Psarakis, 2006; Smyth & Smyth, 2005, Extermann, 2007). None of these articles specifically address the impact cancer and its treatment has on the self-management of diabetes. The importance of diabetes self-management and glycemic control in the cancer patient is emphasized. In order to develop care processes that will ensure continued self-management of diabetes in the older adult who is undergoing treatment for cancer, and understanding of how diabetes self-management is impacted needs to be developed.

The following sections will present an integrative review of the literature focusing on the self-management of diabetes, cancer and multimorbidities, and how each is influenced by individual, clinical and behavioral characteristics of the individual. The current state of the science regarding the association of preexisting diabetes and cancer, the impact of having diabetes and cancer on health related outcomes, and the influence cancer has on diabetes self-management will also be explored.

Diabetes Self-Management

The self-management of diabetes is an essential component of the patient's plan of care. Individuals with diabetes are required to maintain a sometimes complex regimen in order to achieve good glycemic control and prevent complications (Sousa, Zauszniewski, Lea, & Davis, 2005). Poor glycemic control in individuals with diabetes has been associated with the development of cardiovascular and peripheral vascular disease and kidney disease which can be life threatening. In addition, poorly controlled diabetes can have an impact on HRQOL

outcomes, such as physical, social, emotional and cognitive functioning, pain and overall well being (Honish, Westerfield, Ashby, Momin, & Phillippi, 2006). The individual with diabetes will usually perform some type of self-management activity on a daily basis. These activities include monitoring of blood sugars, administering of insulin and/or taking of oral medications, monitoring of diet regimens and the following of an exercise program to assist in the management of and prevention of complications related to their diabetes (Funnell, 2008). The actual performance of diabetes self-management behaviors has been shown to be influenced by various factors. These factors include individual, behavioral and clinical characteristics of the individual with diabetes.

Individual Characteristics

Age. The influence of an individual's age varies among studies and the specific self-management behavior being assessed. Older adults overall tend to have fewer barriers associated with self-management of diabetes when compared to younger adults (Glasgow, Hampson, Strycker, & Ruggiero, 1997; Vijan et al., 2005; Wen, Shepherd, & Parchman, 2004). Age has been found to be a significant predictor of diet self-care with older adults reporting higher levels of diet self-care in a cross-sectional study by Wen et al (2004). Vijan et al (2005) also found diet was less burdensome for older adults when compared to younger adults. Honish, Westerfield, Ashby et al (2006) noted an individual is more likely to be compliant with diabetes treatment as they age. Aljasem et al (2001) noted age was negatively correlated with binge eating, adjusting diet and vigorous exercise, and positively correlated with following an ideal diet. In this study younger individuals were more likely to adjust their diet and participate in vigorous exercise, where older individuals were less likely to binge eat, and more likely to follow an ideal diet. Age has been noted to have a positive or negative influence on the performance of diabetes self-

management behaviors. The relationship of age to the continued performance of self-management behaviors in older adults undergoing chemotherapy is unknown.

Sex. In relation to self-care behaviors, women with diabetes are more likely to participate in exercise and men are less likely to binge eat (Aljasem, et al., 2001). Women are also more likely to report significant disruption of their social lives due to their diabetes (Mann, et al., 2009a). Other studies which have included gender as a variable has not reported any significant differences in self-management behaviors in relation to gender (Coates & Boore, 1998; Toljamo & Hentinen, 2001). These studies that have not found an association between gender and self-management behaviors for diabetes did not look at specific behaviors. Gender differences for diabetes self-management may be behavior specific.

Race/Ethnicity. Few studies have looked at diabetes self-management in specific to race, ethnicity and culture. Aljasem et al (2002) noted race was negatively correlated with skipping medications and Caucasians were less likely to skip their medications than other races. The specific relation of race to performance of self-management behaviors is unclear.

Ethnicity and culture can positively or negatively influence self-management of diabetes (Ponzo et al., 2006; Weiler & Crist, 2009; Wong, Stewart, & Furler, 2009). Ethnicity and culture has an influence on diet, exercise and overall performance of self-management behaviors for diabetes (Castro, O'Tolle, Brownson, Plessel, & Schauben, 2009; Lanting et al., 2008; Sowattanangoon, Kotchabhakdi, & Petrie, 2009; Weiler & Crist, 2009). Lanting et al (2008) studied ethnic differences in outcomes of diabetes in a study conducted in the Netherlands. This study compared native Dutch individuals to immigrants from Turkey or Morocco. Immigrants viewed their Diabetes more seriously, and reported a more positive attitude and higher levels of social support than Dutch participants. Barriers were higher among the immigrants in relation to

diet management, where Dutch individuals had more barriers associated with taking prescribed medications and monitoring of blood glucose levels.

Weiler and Crist (2009) noted in the Latino population, cultural aspects of family, social expectations/perception of "illness" and the social stigma of disease all could have a positive or negative influence on the performance of self-management behaviors for diabetes. Culture also plays a strong influence in how Asians manage their diabetes. In the Thai, Chinese and other Asian populations diabetes is managed according to cultural beliefs and norms (Sowattanangoon, et al., 2009; Wong, et al., 2009; Xu, Toobert, Savage, Pan, & Whitmer, 2008). Race and ethnicity have both been shown to be strong influencing factors for diabetes self-management. The role race and ethnicity play in regards to maintaining self-management behaviors for diabetes when an individual is faced with a new chronic condition such as cancer is missing in the literature.

Financial. An individuals income level can be an influencing factor to how well they comply with and perform required self-management behaviors. Peyrot, Rubin, Kruger and Travis (2010) noted individuals who had higher incomes were less likely to omit or skip an insulin dose. Nagelkerk et al (2006) and Utz et al (2006) both identified cost of supplies and limited resources as barriers to performing diabetes self-management behaviors. Income level has also been noted to have an influence regarding certain behavioral characteristics associated with diabetes self-management. Figaro, Elasy, BeLue, Speroff and Dittus (2009), noted individuals with higher levels socioeconomic status also had higher levels of outcome expectations and self-efficacy, which influenced their compliance with diabetes self-management behaviors. Income level plays a direct role on the performance of self-management behaviors by influencing the individual's ability to afford supplies necessary to carry out self-management

activities. Income level also plays an indirect or mediating role through its association with self-efficacy and outcome expectancies. These behavioral characteristics will be further explored later in this chapter.

Education Level. Findings regarding level of education are consistent across studies. Individuals with lower education perceive more difficulty with diabetes self-management (Aljasem, et al., 2001; Mann, et al., 2009a; Rhee et al., 2005). Mann et al (2009) noted individuals with less than high school education were more likely to believe that they actually had diabetes, they felt they only had diabetes when glucose levels were high. Individuals who did not perceive their glucose levels as being high were less likely to take medications as prescribed. Aljasem et al (2001) noted individuals with higher levels of education tested their blood glucose more frequently. Current research has shown that the education level of the individual can have an impact on the performance of diabetes self-management behaviors, with individuals with higher levels of education being more likely to perform diabetes self-management activities.

Marital Status. Self-management behaviors for diabetes can be influenced by spouses and other family members (De Ridder, Schreurs, & Kuijer, 2005; Ponzo, et al., 2006). Having a good support person such as a spouse who is willing to engage with the patient in regards to self-management is identified as a factor which improves self-management behaviors in individuals with diabetes (Nagelkerk, et al., 2006). Tolijamo & Hentinen (2001) noted individuals who lived alone had poorer Hbg A1c's than those living with a family or partner. Individuals who perceive higher levels of support from spouses and other family members who may be living with them are less likely to neglect self-management behaviors (Toljamo & Hentinen, 2001; Wen, et al., 2004). The influence of marital status is dependent upon how much spousal support the

individual perceives. The presence of other individuals in the home can have a positive effect on the performance of diabetes self-management behaviors.

Summary

Many of the studies which have explored the relationship between individual characteristics and self-management of diabetes have been qualitative or used a descriptive, correlational or cross-sectional design. These studies show individuals who have had the disease longer, are older, have higher education, and higher levels of income are more likely to have better diabetes self-management. Race/ethnicity/culture, marital status, sex and living arrangements also play a role in the self-management behaviors for diabetes in adults. In addition, many of these studies excluded individuals who had life threatening conditions, or complex or competing chronic illnesses. None of these studies specifically addressed issues that may occur when an individual develops a new competing comorbid condition such as cancer. Are individuals with diabetes likely to sustain their level of self-management behaviors over time when faced with a new chronic illness that may be perceived as more life threatening, and causes the development of competing demands related to the addition of a new complex condition, which adds to the complexity of the disease management regimen?

Clinical Characteristics

Across the diabetes self-management literature four different clinical characteristics which impact diabetes self-management can be identified. These are: diabetes related complications, number of comorbidities, competing nature of comorbidities and the diabetes regimen (Aljasem, et al., 2001; Kerr, et al., 2007; Utz et al., 2006). The length of time an individual has had diabetes can also be a factor which influences how well they perform diabetes self-management behaviors. Longer duration of diabetes has been noted to be significantly

associated with lower diabetes self-management (Ponzo, et al., 2006). Reasons for this association may be due to the facts that individuals who have had diabetes longer may have more diabetes related complications, developed other competing comorbid conditions and may have a more complex regimen to follow in order to manage their diabetes.

Aljasem et al (2001) noted skipping meals was higher among individuals with more diabetes related complications. Kerr et al (2007) noted that the greater number of comorbidities and individual had, the lower was their diabetes self-management ability and prioritization. Kerr et al (2007) also noted that individuals with discordant conditions, such as pulmonary disorders or heart disease had lower self-management ability. Utz et al (2006) and Morrow et al (2008) both conducted qualitative studies exploring diabetes self-management. Participants in both of these studies also cited the discordant nature of both chronic and acute illness impacted their self-management. The management of discordant competing conditions impacted their ability to control glucose levels and follow their self-care regimen due to the interference from medications and/or other prescribed treatments for the competing conditions (Morrow, Haidet, Skinner, & Naik, 2008; Utz, et al., 2006).

The complexity of the self-management regimen itself has also been noted by individuals with diabetes as a barrier to effective self-management. (Mann, et al., 2009; Utz, et al., 2006; Vijan, et al., 2005). In a study by Mann et al (2009) which sought to identify potentially modifiable factors related to poor medication adherence among individuals with diabetes found that regimen complexity correlated with poor adherence to taking medications. In a qualitative study by Utz et al (2006), the complexity of knowing what to do to manage diabetes, and fitting the complex regimen into their life were identified as barriers to effective self-management by rural African Americans who participated in this study. Regimen complexity may be confusing

to some individuals with diabetes, when it comes to making decisions regarding management of high or low blood glucose levels, and how best to adjust other components of their regimen (Mann, et al., 2009; Utz, et al., 2006). For individuals who have a more complex regimen or who's regimen complexity changes, they may be less likely to perform self-management activities as recommended.

Summary

Consistently across studies, the complexity of plan of care and the number of comorbidities have been identified as a barrier to diabetes self-management. Very few studies have looked at the relationship between comorbidities and actual diabetes self-management. The study by Kerr et al (2007) was the only study found by this investigator which explored the relationship between comorbid conditions and diabetes self-management. This study used a cross-sectional observational design and did not look at changes in self-management behaviors in adults when a new chronic condition develops. Kerr et al (2007) did consider cancer to be a discordant condition, which can have an impact on diabetes self-management. From the literature it is unknown if individuals will maintain the same level of diabetes self-management when faced with a new complex comorbid condition.

Behavioral Characteristics

Self-Efficacy. Self-efficacy has been noted to be an important influential factor related to successful diabetes self-management and has been found to be positively correlated with the performance of self-management behaviors (Aljasem, et al., 2001; Sousa, et al., 2005; Wen, et al., 2004;Williams & Bond, 2002). Only one study found by this author found no significant relationship between self-efficacy and performance of self-management behaviors for diabetes (Chlebowy & Garvin, 2006). Individuals with high diabetes self-efficacy are more likely to

follow an ideal diet and adjust their insulin as need, are less likely to skip testing of blood glucose levels and taking of their medications (Aljasem, et al., 2001;Williams & Bond, 2002). Self-efficacy has also been noted to be a significant predictor of exercise self-care in individuals with diabetes (Wen, et al., 2004;Williams & Bond, 2002).

An individual's level of self-efficacy is an important factor associated with the performance of self-management behaviors for diabetes. For individuals with higher levels of self-efficacy are more likely to perform self-management behaviors and have higher levels of self-management than those with lower levels of self-efficacy. What role does self-efficacy play in individuals who have diabetes and then develop a new chronic condition such as cancer? Are these individuals still likely to maintain the same level of self-management for their diabetes or will this change? Some studies have looked to see if the level of self-efficacy in individuals with diabetes could be changed through education. Studies have found the level of self-efficacy will improve or increase with education and as self-efficacy improves so does diabetes self-management. (Atak, et al., 2008; Shah & Booth, 2009; Trief, Teresi, Eimicke, Shea, & Weinstock, 2009). Studies which address the association between diabetes specific self-efficacy and ability to maintain self-management behaviors when faced with a new chronic condition are missing in the literature.

Outcome Expectancies. Very few studies have included outcome expectancies (OE) of the individual as part of the study. OE has been noted to be significantly related to the performance of self-care behaviors (Chlebowy & Garvin, 2006; Mann, et al., 2009;Williams & Bond, 2002). The more an individual believes that their overall diabetes management impacts their outcomes, the more likely they are to perform self-management behaviors (Chlebowy & Garvin, 2006). All of these studies are descriptive or correlational in design, using a cross-

sectional survey approach. None of these studies report information regarding comorbidities, and if there is a moderating or mediating effect between OE and other comorbidities on the performance of diabetes self-management activities. The influence OE has on the performance of diabetes self-management behaviors in individuals with diabetes, who have developed a new competing illness, such as, cancer is currently unknown.

Anxiety/Depression. Both depression and anxiety have been noted to have a negative impact on the performance of self-management behaviors for diabetes (Aikens, et al., 2008; Bai, et al., 2009; Ciechanowski, Katon, & Russo, 2000; Egede, et al., 2009; Gonzalez, et al., 2007; Hall, et al., 2009; Lin et al., 2004; Luyster, et al., 2009). Individuals who with higher levels of depression have poorer glycemic control and are less likely to follow the recommended diet and exercise regimens (Aikens, et al., 2008; Bai, et al., 2009; Ciechanowski, et al., 2000; Gonzalez, et al., 2007; Hall, et al., 2009). The presence of anxiety may increase the likelihood of avoidance behaviors due to fear associated with adverse outcomes (Hall, et al., 2009). The impact anxiety and depression has on diabetes self-management in individuals who are undergoing treatment for cancer is unknown. Existing studies have either excluded individuals with life threatening illnesses, or complex comorbidities such as cancer from the study, or information regarding comorbidities was not considered during the analysis.

Summary

Behavioral characteristics play an important role in regards to how well or how much an individual will perform self-management behaviors for their diabetes. The role these play in the continued performance of self-management activities when an individual is faced with a new and complex illness such as cancer is unknown. This study seeks to begin to fill this gap by exploring the relationship between diabetes self-management behaviors in individuals who are

undergoing treatment for a recently diagnosed cancer, and the behavioral characteristics of self-efficacy, outcome expectancies and depression/anxiety. Like diabetes, individuals with cancer also perform self-management activities. Cancer self-management will be explored in the next section.

Cancer Self-Management

The literature related to self-management in cancer, primarily focuses on the management of cancer and cancer treatment related symptoms. Cancer and its treatment can cause a myriad of symptoms in which patients will perform self-management strategies for (Dodd, 1988; Janz, et al., 2007; Miaskowski, et al., 2004;Williams, et al., 2006), Individuals undergoing chemotherapy have reported experiencing up to 14 different symptoms (Chou, et al., 2007). In a study by Janz et al (2007) that explored the symptom experience of women following primary breast cancer treatment, over half the women in the study (study N= 1372) reported symptoms related to fatigue, hot flashes, sleep disturbance and general pain. Given et al (2001) in a study which examined the co-occurrence and patterns of change among symptoms in newly diagnosed cancer patients found pain and fatigue were more likely to occur within 40 days of concluding chemotherapy, radiation and/or surgery. Patients with 3 or more comorbid conditions had significantly more symptoms.

Common symptoms associated with chemotherapy that have been reported are lack of energy, hair loss, dry mouth, nausea, feeling sad, sleep difficulty, mouth sores, loss of appetite, numbness in fingers and/or toes, and fatigue (Chou, et al., 2007;Williams, et al., 2006). Rao & Cohen (2004) noted symptoms in elderly cancer patients usually overlap and include nausea, vomiting, pain, depression, fatigue, insomnia, loss of appetite, and increased anxiety. Fatigue is one of the most commonly reported symptoms in older cancer patients (Rao & Cohen, 2004).

Many older adults will have pre-existing comorbid disease when diagnosed with cancer (Rao & Cohen, 2004; Reiner & Lacasse, 2006). The severity of symptoms experienced in the older cancer patient is associated with having three or more pre-existing comorbidities (Reiner & Lacasse, 2006). Kurtz et al (2001) noted patients with higher symptom severity scores had more comorbid conditions, were more depressed and experienced greater physical functioning deficits. Many older adults with cancer will use self-management strategies to manage their symptoms.

Self-management strategies for these symptoms include making dietary changes, taking medications, resting or taking a nap (Williams, et al., 2006). The use of self-management strategies have been found to provide relief of these symptoms (Borthwick, et al., 2003; Dodd, 1988; Magnan, 2004). Studies have found that the use of self-management strategies will provide up to moderate relief for many of these cancer related symptoms (Chou, et al., 2007; Dodd, 1988; Magnan, 2004; Miaskowski, et al., 2004).

Actual factors which influence the use of self-management activities for symptoms in cancer patients is scarce in the literature. A recent study by Hoffman et al (2009) found perceived self-efficacy for fatigue self-management predicted greater physical function status, and mediated the relationship between cancer related fatigue severity and physical function status. This study did not look at the relationship between perceived self-efficacy and actual performance of fatigue self-management strategies.

Summary

The cancer literature which addresses self-management primarily focuses on the self-management of symptoms associated with cancer and its treatment and highlights the nature and frequency of symptoms in adults with cancer undergoing treatment. The presence of cancer related symptoms can also impact the overall physical functioning of the individual with cancer

which could impact ability to perform certain self-management activities, such as exercise for diabetes. Several researchers have looked at the use of different interventions in order to improve the symptom experience for individuals receiving cancer treatment. The impact of having to perform self-management activities for these symptoms on the performance of self-management activities for diabetes is unknown. Will individuals with diabetes be less likely to continue to perform self-management behaviors for their diabetes in the presence of these symptoms and other requirements for cancer care? Kerr et al (2007) noted that patients with diabetes who have an illness that they perceive more severe or life threatening such as cancer, will ignore their diabetes and required self-management behaviors. The impact of having multi-morbidities on self-management will be explored in the following section.

Self-management of Multi-Morbidities

The literature regarding the self-management of multi-morbidities by older adults is limited. Over the past decade various researchers have started to study this phenomenon. The majority of individuals 65 and older will have more than one chronic condition they will need to self-manage. Bayliss et al (2003) conducted a qualitative study to identify perceived barriers to self-management in individuals with multiple chronic conditions. Barriers to self-management were related to individual, clinical and behavioral characteristics. Each of these characteristics will be further explored and then an overall summary will be presented at the end of the section.

Individual Characteristics. Characteristics related to cost/financial status, social support and age have been noted to be barriers to self-management in individuals with multiple morbidities (Bayliss, J. Ellis, & J. Steiner, 2007; Bayliss, Ellis, & Steiner, 2008; Bayliss, Steiner, Fernald, Crane, & Main, 2003). Bayliss et al (2008) noted that age was related to increased

disease burden in individuals with multiple morbidities. This increased disease burden has been noted to interfere with the self-management for a chronic illness.

The financial burden of caring for multiple chronic conditions has been noted in more than one article (Bayliss, et al., 2007, 2008;Bayliss, et al., 2003; Jerant, et al., 2005; Piette & Kerr, 2006; Schoenberg, et al., 2009). Financial constraints noted in the literature were related to increased out of pocket cost due to the increased number of medications and dietary recommendations (Bayliss, et al., 2003; Schoenberg, et al., 2009). In a qualitative study by Schoenberg et al (2009) participants expressed challenges related to medication and dietary adherence due to finances.

Social support that is perceived to be lacking has also been noted to create a barrier in the management of multiple morbidities by adults. Bayliss et al (2008) in a qualitative study which explored process of care desired by elderly individuals with multi-morbidities, identified sources of support as factor which modified the individuals daily routine. The reason for this impact on actual self-management was not identified in this study. Jerant et al (2005) in a qualitative study which explored perceived barriers to self-management noted lack of support from family as being a barrier. Specific barriers identified by participants in the study were: family members who did not perceive the individual as being "sick" and spouses who were not supportive of weight loss efforts or who would cook inappropriate foods (Jerant, et al., 2005). Social support which is perceived as negative or lacking can impact how well a patient performs self-management behaviors for one or more chronic conditions.

Clinical Characteristics. The impact or relationship of clinical characteristics associated with having multiple comorbidities on self-management has been noted frequently in the literature (Bayliss, et al., 2007, 2008; Bayliss, et al., 2003; Jerant, et al., 2005; Kerr, et al.,

2007; Noel, Frueh, Larme, & Pughs, 2005; Piette & Kerr, 2006; Proctor, Hasche, Morrow-Howell, Shumway, & Snell, 2008; Schoenberg, et al., 2009). These clinical characteristics include the total number of medications the individual takes, the compounding effects, and the number of, as well as the severity of the symptoms, the individual experiences that are associated with his comorbidities. The overall disease burden of the different comorbidities and the concordance or discordance of the comorbidities is also considered a clinical characteristic which can act as a barrier to effective self-management.

The total number of medications required by individuals with multiple morbidities was identified as a barrier to self-management in a study by Noel et al (2005). Barriers associated with the total number of medications were related to the difficulty of the medication regimen, and the adverse effects associated with the medications (Noel, et al., 2005). Similarly, participants in a qualitative by Bayliss et al (2003) noted the compounding effects, therapeutic effects and side effects of medications presented a barrier to self-management. In this same study, participants noted the schedule and actual coordination of having to take multiple medications, also created a barrier to self-management of their different co-morbidities (Bayliss, et al., 2003).

The compounding effects of multiple comorbid conditions have been noted most in the literature as a barrier to self-management for the different multimorbidities. These compounding effects can be placed into three different categories: disease burden, disease concordance and symptoms. *Disease burden:* the burden of dominant effect of a single condition was noted by Bayliss et al (2003) as a barrier to self-management. This compounding effect or increased burden impacted the ability to exercise in individuals with diabetes due to difficulty in breathing. Kerr et al (2007) noted that higher burden associated with multiple morbidities was associated

with lower self-management. This disease burden is associated with the concordance or discordance of the multiple conditions an individual may have and the symptoms associated with each disorder.

Disease Discordance: Discordant condition are conditions which do not follow a similar disease management plan and are not part of the same overall pathophysiologic risk profile of an individual (Piette & Kerr, 2006). Hypertension and Diabetes would be considered concordant, diabetes and cancer would be discordant. Individuals with discordant conditions have lower self-management prioritization and lower self-management ability (Kerr, et al., 2007). This discordance between medical problems can cause a competition for time, attention and priority for older adults and impact their self-management of one or more of their chronic conditions (Proctor, et al., 2008).

Symptoms: Patients with multiple morbidities also experience multiple symptoms, and the compounding effects of their conditions may increase their total symptom severity and symptom burden (Bayliss, et al., 2007, 2008; Jerant, et al., 2005; Noel, et al., 2005). Bayliss et al (2007) noted depressive symptoms created a barrier to the self-management of chronic conditions in older adults with multiple morbidities. The risk of, or presence of depression increases in individuals with comorbid conditions (Egede, 2005; Simon, 2001), and the presence of depression in individuals with diabetes has been noted to decrease adherence to diet, exercise and medication regimens (Egede, et al., 2009; Gonzalez, et al., 2007). Depression has also been associated with poorer perceived health status and functional ability (Egede, et al., 2009). Symptoms of decreased mobility, physical limitations, fatigue, pain, dizziness, shortness of breath and insomnia were noted by Noel et al. (2005), as being issues for individuals with multi-morbidities which can impact self-management.

Behavioral Characteristics (self-efficacy). Bayliss et al (2003, 2007) noted level of self-efficacy to be a barrier to self-management in individuals with multiple morbidities. Wasson, Johnson and Mackenzie (2008) in a cross-sectional longitudinal survey looking at factors associated with self-management found individuals with higher confidence were more likely to perform self-management behaviors. Individuals with persistent high levels of self-efficacy were better engaged in everyday activities and self-management (Wasson et al., 2008). Gallagher, Donoghue, Chenoweth and Stein-Parbury (2008) in a prospective descriptive study looking at the relative influence of self-efficacy on self-management behaviors in older adults with chronic illness found self-efficacy to predict both concurrent and future self-management. Individuals with higher levels of self-efficacy were more likely to sustain their self-management behaviors (Gallagher et al., 2008).

Self-efficacy has also found to partially mediate the negative relationship of having more than one chronic health condition and ability to exercise (Krein, Heisler, Piette, Butchart, & Kerr, 2007). Krein et al (2007) in a cross-sectional survey examined how chronic pain affected difficulty with recommended self-management activities, found higher self-efficacy was associated with significant lower odds of reporting difficulty with exercising. Self-efficacy plays an essential role in the performance of self-management behaviors. Individuals with higher levels of self-efficacy are more likely to engage in self-management behaviors when compared to those with lower levels of self-efficacy.

Summary

The limited nature of the studies regarding the relationship of self-management in individuals with multimorbidities identifies barriers similar to those in individuals with a single morbidity such as diabetes: age, financial status, social support and self-efficacy. In addition,

this literature identifies specific issues regarding having multiple conditions: symptoms, complexity of care, disease concordance and overall disease burden as barriers to self-management. These few studies have been mainly qualitative in nature and have not actually explored the relationship between these variables and/or their impact on self-management behaviors in adults with diabetes. Further studies need to be done in order to address how much the self-management for one chronic condition may be impacted by another and what factors might be associated with changes in self-management behaviors in this population. None of these studies have specifically looked at the impact cancer may have on continued self-management of diabetes or other chronic conditions.

Cancer & Diabetes

Studies which explore the relationship between cancer and diabetes self-management are absent in the literature. Most literature looking at the relationship of diabetes and cancer focuses on complications or outcomes associated with cancer and its treatment (Attili, et al., 2007; Barone, et al., 2008; Srokowski, et al., 2009). Attili et al (2007) noted individuals with diabetes with good glycemic control are at equal risk for complications when compared with non diabetics, diabetes is associated with an increase in mortality and poor response rates to treatment. In a literature review by Psarakis (2006) noted individuals with diabetes and cancer have a poorer prognosis, higher infection rates and shorter remission periods than those without diabetes. Hyperglycemia in diabetes was noted to be one of the factors associated with these poorer outcomes (Psarakis, 2006).

The glucocorticoids used in cancer treatment protocols impact glucose levels in individuals with cancer and diabetes (Leak, et al., 2009; Psarakis, 2006). In addition to glucocorticoids, the possible impact symptoms and changes in diabetes self-management may

also affect glycemic control. Nausea and vomiting may impact the patients ability to eat and drink impacting their ability to continue to follow their diabetic diet. Fatigue and pain may have an impact on the individuals activity level. Patients undergoing chemotherapy with diabetes are at risk for hypoglycemic as well as hyperglycemic episodes which can impact their symptom severity and how they self-manage their diabetes (Leak, et al., 2009; McCoubrie, et al., 2005).

Individuals who are on insulin to control their diabetes need to be willing to make necessary changes to their insulin regimens, as well dietary and exercise regimens used to manage their diabetes (Leak, et al., 2009; Psarakis, 2006). Individuals with diabetes and cancer may also need to increase the frequency of blood glucose monitoring, especially if they are on steroids, or are having nausea, vomiting, or changes in appetite and food tolerance (Psarakis, 2006). In order to achieve the best outcomes for individuals with diabetes and cancer, health care providers need to have an understanding of the complexities of both diseases (Smyth & Smyth, 2005). A collaborative team approach between the patient's primary diabetes care provider and their oncology provider needs to be developed in order to prevent and minimize complications and quality of life in individuals with cancer and diabetes (Smyth & Smyth, 2005). Individuals who have good glucose control have been shown to have lower infection rates than those with poor glucose control while undergoing treatment for cancer (Psarakis, 2006).

In summary, this literature which addresses the relationship between cancer and diabetes primarily focuses on the possible interaction between cancer treatment and diabetes outcomes such as glycemic control. The literature also identifies the increased risk of mortality, morbidity and infection in individuals with diabetes and cancer (Barone, et al., 2008, 2010; Folsom, Anderson, Sweeney, & Jackobs, 2004; Giovanucci et al., 2010; Meyerhardt et al., 2003). One non-research article did begin to highlight the importance of continued diabetes self-management

by individuals undergoing treatment for cancer (Psarakis, 2006). None of the studies or articles have actually looked at changes in diabetes self-management in patients undergoing treatment for cancer. In order to understand how to best care and support individuals with diabetes and cancer, an understanding needs to be developed regarding the patients perceptions of how their cancer has impacted their ability to care for their diabetes. In addition, a understanding of what specific factors may influence or predict changes in the self-management of diabetes in adults with cancer needs to be developed.

Summary

Diabetes and cancer are two common chronic diseases in today's society. The number of individuals who have both cancer and diabetes may steadily increase over the next several years as the population ages. Both diabetes and cancer commonly occur in individuals over the age of 50. Self-management is considered an essential component in the plan of care for individuals with diabetes and/or cancer. Several factors can influence if an individual will perform recommended self-management behaviors. Individual, clinical and behavioral characteristics of an individual all can influence the actual performance of self-management behaviors.

For the individual with diabetes, individual or socio-demographic factors have been shown to have either a positive or negative influence on the performance of self-management activities. Clinical characteristics such as disease severity, length of time with the illness, symptom burden and other comorbidities all can influence how well an individual performs self-management behaviors. What is not as well known is how a change in the patients clinical situation may impact their self-management, specifically the development of a new and possibly competing disorder, such as cancer. It has been hypothesized that individual with diabetes will

prioritize a disease that they consider more severe or life threatening over their diabetes, and be less likely to follow their recommended regimen (Kerr, et al., 2007; Piette & Kerr, 2006).

Behavioral factors such as depression, self-efficacy and outcome expectancies all have been shown to play a role in the performance of self-management activities. How these impact or are related to the continued performance of self-management activities in individuals with diabetes who are undergoing treatment for cancer is unknown. One can hypothesize that individuals who have higher levels of self-efficacy, outcome expectancies and lower levels of depression and anxiety will more likely continue to perform their self-management activities for their diabetes, while they are undergoing chemotherapy for cancer treatment.

We know that individuals with cancer and diabetes have higher mortality rates, are more likely to develop complications such as infections, and are more likely to be hospitalized when compared to those with cancer only (Barone, et al., 2008; Giovanucci, et al., 2010; Psarakis, 2006). It has been hypothesized that glycemic control may play a role in regards to how well a patient may respond to or tolerate treatment (Giovanucci, et al., 2010; Psarakis, 2006). The performance of self-management behaviors by individuals with diabetes has been shown to improve glycemic control (Honish, et al., 2006; Sousa, et al., 2005). On can hypothesize that if the performance of self-management behaviors decrease in individuals while they are undergoing chemotherapy, they may have worse glycemic control and be more likely to develop complications. It is important to determine how cancer and its treatment may impact diabetes self-management in adults while they are undergoing chemotherapy.

The literature in this chapter identified many of the factors which can influence the actual performance of self-management behaviors for individuals with diabetes or cancer. The development of cancer in individuals with pre-existing diabetes may produce a competition or

interaction between recommended treatments and self-management behaviors that may impact their ability to adhere to treatment or their ability to comply with recommended self-management behaviors (Terret, et al., 2007). As nurses and health care providers we need to understand the competition which may occur in older adults, between cancer and co-morbidity self-management in order to provide safe and efficacious care to the older adult population with cancer. This exploratory study seeks to fill the gaps in our knowledge and add to the current research in relation to the impact cancer has on self-management of diabetes in older adults receiving chemotherapy.

Chapter 4

Methods

This pilot study utilized a written self-administered survey at baseline and a phone survey 8 weeks later. The phone survey included two open-ended questions. Written surveys were given to the potential participants by nurses at each of the study sites. These surveys were part of a packet which also included two consent forms, a study brochure and a self-addressed stamped envelope for the participant to return the written survey and a signed consent form to the study investigator. Phone surveys were completed by the study investigator 8 weeks after the participant was enrolled in the study. The open ended questions were tape recorded with the participants permission for the purpose of transcription for analyses.

Study Subjects

Inclusion Criteria. The sample consisted of individuals who were50 years of age or older with Type I or II diabetes and a diagnosis of a solid tumor cancer, who were eligible for or currently undergoing outpatient intravenous or oral chemotherapy. In addition participants needed to be on daily insulin or an oral hypoglycemic for their diabetes, be able to read, write and speak English, be able to follow verbal and written instructions and have access to and be able to use a telephone.

Exclusion Criteria. Participants were excluded if they were unable to hear or use a telephone as well as individuals who were unable to understand written and verbal communication or had a self-reported history of Alzheimer's or Dementia.

Design for Sampling

A convenience sample of individuals meeting the study criteria was obtained from eight different cancer centers in the states of Michigan and Ohio. A rolling enrollment was utilized until an adequate number of participants had been recruited.

Recruiting subjects. Recruitment began once IRB approval from Michigan State University and the individual cancer centers was obtained. Potential participants were identified by specific clinic staff who had agreed to assist in the recruitment of participants. These individuals were provided with a check list of the inclusion and exclusion criteria to assist them in identifying potential participants. Final screening for participation was done by the study investigator after the consent had been received. Once a participant was identified, the clinic staff provided them with a study information packet, which included a study brochure, consent form, initial survey and self-addressed stamped envelope to return the completed survey and consent to the study investigator. Cancer center staff had an educational session provided by the study investigator regarding the study protocol, inclusion and exclusion criteria. If a participant agreed to participate they were asked to return the signed consent along with the completed initial survey and contact information to the study investigator.

In addition to the recruitment by staff members in the clinic, flyers were posted in the waiting areas and exam rooms of the clinics informing patients about the study. The flyers asked the patients if interested in participating to discuss with their provider or clinic nurse. In addition, fliers were posted in the conference room where the classes were taught as well as in the waiting rooms.

Study Settings. *Sparrow Regional Cancer Center* located on the Campus of the Sparrow Health System in Lansing, Michigan treats approximately 9500 individuals per year, and is accredited by the American College of Surgeons Commission on Cancer. The Sparrow Regional Cancer Center, utilizes a multidisciplinary approach employing combinations of cutting-edge techniques in treating cancer. The regional cancer center at sparrow utilizes oncological surgery, chemotherapy, radiation and drug therapies as part of their individualized treatment programs for

each individual. The Sparrow Regional Cancer Center has an extensive clinical trials program and is a member of the Michigan Cancer Research Consortium and is a state leader in clinical trials. Through this consortium, access to the innovative protocols at M.D. Anderson, Mayo Clinic and the National Cancer Institute are made available to patients seen and treated at the cancer center.

MSU Breslin Cancer Center, also located in Lansing, Michigan, is a full service outpatient based community cancer care facility and sees approximately 900 individuals per year. MSU Breslin Cancer Center is a member of the Great Lakes Cancer Institute (GLCI). The GLCI is a non-profit partnership between Michigan State University and McLaren Health Care. The MSU Breslin Cancer Center utilizes an interdisciplinary team approach for coordinated, comprehensive, individualized treatment planning and has a dedicated chemotherapy outpatient infusion center. The MSU Breslin Cancer Center has a clinical trials office which matches patients who qualify for regional or nationally approved clinical trials. The MSU Breslin Cancer Center has received the 10 star Community Investor Award through the American Cancer Society, Great Lakes Division.

Allegiance Health Cancer Center is located in Jackson Michigan, and provides cancer care to over 800 individuals per year. The cancer center at Allegiance Health is part of the Ray H. Clark Cancer Research Program and has an affiliation with the University of Michigan (UOM) Cancer Center Network. As part of the UOM cancer network, Allegiance has access to University-based clinical trials, allowing individuals to be treated close to home with the latest therapies. Oncologist at Allegiance health provides chemotherapy, immunotherapy and hormone therapy options to patients for over 30 years. The cancer center at Allegiance Health has been awarded the American College of Surgeon Commission on Cancer Care certification. Allegiance

Health also participates in many national clinical trials. Allegiance Health Cancer Center is one of 50 participating research programs which has a collaborative relationship with the NCI clinical trial programs through the Michigan Cancer Research Consortium Community Clinical Oncology Program.

West Michigan Cancer Center (WMCC) located in Kalamazoo, Michigan is a collaborative oncology practice between Borgess Medical Center, and Bronson Methodist Hospital. WMCC averages over 80,000 patient visits a year. WMCC provides a broad range of diagnostic and treatment services, including onsite radiation and chemotherapy. WMCC participates in multiple clinical trials and is a member of the National Cancer Institute.

Red Cedar Oncology is a private oncology practice located in East Lansing, MI. The practice consists of one oncologist, a physician assistant and a nurse practitioner who specialize in oncology care. Red Cedar Oncology has approximately 3840 patient visits per year. The office participates in various clinical trials, and provides onsite chemotherapy.

Munson Medical Center Infusion Clinic is part of the Munson Healthcare organization and is located in Traverse City, MI. The infusion clinic sees approximately 8,000 patients per year, and provides multiple services, including chemotherapy administration. The Infusion clinic participates in many clinical trials supported by the National Cancer Institute and is a member of the Grand Rapids clinical Oncology Program.

University of Toledo Cancer Center (UTCC) is located on the campus of the University of Toledo Medical Center in Toledo, Ohio. UTCC is a comprehensive cancer center which provides evaluation, diagnosis and treatment for all forms of cancer. UTCC has approximately 1056 new patients per year which are seen for cancer treatment. UTCC offers and participates in

multiple clinical trials and collaborates with the Jacobson Center for Clinical & Translational Research.

Great Lakes Cancer Institute – Flint (FCC) is located in Flint, Michigan. FCC provides comprehensive state of the art cancer treatment, including radiation and chemotherapy. FCC is accredited by the commission on cancer and the American college of surgeons. FCC sees over 800 patients per year. FCC participates in multiple clinical trials and is a member of the Clinical Cancer Research Center, which is a collaborative between all of the Great Lakes Cancer Institute Centers.

Data Collection

The initial survey was written at a Flesh-Kincaid 8th grade reading level, and the reading level was checked by using the Flesh-Kincaid readability assessment tool in Micro-soft word and determined to be at an 8th grade level. Once the consent and initial survey was obtained the study investigator contacted the potential subject to reconfirm their willingness to participate in the study and further establish if they meet study criteria, and set up times for the subsequent survey to be administered by telephone. This interview took approximately 20 minutes. Participants were contacted at 6 weeks, to set up a time for the follow up survey to be completed.

Study Measures

This study utilized multiple different established instruments to measure each of the study variables. Table 1 provides a summary of the variables and the instruments being used to assess each of the variables in the study.

Table 1:

Variables & Measurement for study

	Variable type/Collection Time	**# of items**	**α**	**Estimated Time to Complete**
Individual Characteristics				
Socio-demographics: (Age, sex, education level, income status, race/ethnicity marital status and living arrangement)	Covariates/ Baseline	6		3 minutes
Clinical Characteristics				
Co-morbidities Type and Number	Predictor/ Baseline	10		5 minutes
Generic Symptoms – Symptoms of Illness check List	Predictor/ Baseline and 8 week follow up	33	.86	5 minutes
Diabetes: Length of Illness, Insulin or non-insulin, Number of medications,	Predictor/ Baseline	3		1 minute
Diabetes Severity: *Diabetes Complications Index (DCI)*	Predictor/ Baseline	10		10 minutes
Cancer: Type and Stage, Type of Chemo, Chemo frequency/Schedule, Cancer Meds	Predictor/ Baseline	4		2 minute
Behavioral Characteristics:				
Perceived Diabetes Self-Efficacy: *Confidence in Diabetes Self-Care Scale*	Predictor/ Baseline	20	.90	10 Minutes
Outcome Expectancies: *Outcome Expectancies subscale of the Multidimensional Diabetes Questionnaire (MDQ)*	Predictor/ Baseline	6	.86	3 minutes
Depression/Anxiety: *Hospital Depression and Anxiety Scale (HADS):* *Depression subscale* *Anxiety subscale*	Predictor/ Baseline	 7 7	 .89 .86	5 minutes total for both scales
Diabetes Self-Management Behaviors				
Self-Care Inventory-R	Outcome – Baseline & 8 week follow up	15	.87	10 minutes
Cancer Impact on Diabetes Self-management Scale (Based on the illness Intrusiveness Rating Scale)	Predictor – 8 week follow up	5		2 minutes
Total - Baseline		**140**		**65 minutes**
Total –8 weeks		**53**		**22 minutes**

Individual Characteristics. Individual characteristics included the socio-demographic variables of age, sex, education level, income status, marital status, race and ethnicity. Age was measured as a continuous variable based on patients date of birth. Sex was treated as a dichotomous categorical variable, identifying male or female sex. Education level was measured by asking the participant to classify their highest level of education on a 7 point scale, ranging from no formal education to completed graduate/professional degree. Marital status was measured with a 5 point scale, which asks the individual to identify their current marital status. Income status was measured using a 7 point scale asks individuals what their combined household income was the prior year and ranges from less than $24,999 to $150,000 or above. For race, individuals were asked to identify what race they consider themselves, Caucasian/White, African American/Black, Mexican American/Hispanic/Chicano, Native American/Alaskan, Oriental/Asian/Pacific Islander or Other. Ethnicity was assessed by asking individuals to identify themselves as either Hispanic or Latino or not Hispanic or Latino.

Clinical Characteristics. Diabetes specific and Cancer specific clinical characteristics were obtained. In addition, general symptoms and number of comorbidities were also obtained. Comorbidities were assessed using a modified version of the Katz's Comorbidity Questionnaire (Katz, Chang, Sangha, Fossel, & Bates, 1996). This questionnaire asked patients if they have a specific condition and has been used in older patients (Katz et al., 1996). This questionnaire allowed for simple counting of the chronic diseases using a self-report method. The original Katz comorbidity questionnaire was tested in 170 patients and was found to have a test-retest reliability of .91 and had a spearman correlation of .63 was noted between the comorbidity questionnaire and the Charlson index (Katz et al., 1996). Comorbidities will be recorded as a total number for analysis.

General symptoms at baseline were obtained using the Symptoms of Illness Checklist (SIC). The SIC was developed to be a comprehensive measurement of physical illness, that could be used to measure psychological influences on physical health (Stowell, Hedges, Key, & Bloch, 2009). This tool measures 33 different common symptoms associated with illness and disease, the frequency of the symptom and the interference of the symptom on daily function. The frequency of the symptom is measured by asking the number of days over the past two months they had experienced the symptom on a 6 point scale, 0 being none and 5 being daily. For this study participants were asked how many days they have experienced the symptom over the past 2 weeks. The interference with daily function is measured by having the patient rank on a 4 point scale, in which 1 is no interference with daily activities and 4, severe interference. The SIC has a Cronbachs alpha of .86 (Stowell et al., 2009). This instrument was tested in 520 individuals from four different samples, the mean age ranged from 22.7 with a sd of 2.8 years to 45.8 with a sd of 14.1 years. Participant self-report in one of the samples was compared with scores from physician interviews in order to establish concurrent-criterion validity. The scores from patient self-report were similar to those obtained from the physician interviews. The Cohen's Kappa coefficients for the presence or absence of symptoms ranged from .48 – 1.0 for all items (Stowell et al., 2009). This tool was selected for this study for it assesses symptoms associated with both chronic disease and cancer. Baseline symptoms will be entered as total number of symptoms as well as a total severity score. A severity score for each symptom is obtained by multiplying the frequency by the level of impact or interference. Then all severity scores are summed to form a total severity score.

Diabetes specific clinical characteristics included measurements for length of illness, type and number of medications. Length of illness was obtained by asking patients how many years

they have had diabetes and was treated as a continuous variable. Type of diabetes was based on if they are insulin dependent or non-insulin dependent and was classified as a categorical variable. Number of medications was measured by asking patients how many different medications they take for their diabetes and was treated as a continuous variable. In addition, individuals were asked the total number of medications they take daily, in addition to their diabetes medications and was entered as a continuous variable.

Cancer specific clinical characteristics included type and stage of cancer, type of chemotherapy, number of medications they are on for their cancer and cancer symptoms. For cancer type and stage, patients were asked what type of cancer they have, and if they have early or late stage cancer. Type of chemotherapy was classified as intravenous, oral or both. Patients were also asked if they had been treated with radiation or were currently receiving radiation treatments. Number of medications was measured by self-report by asking patients how many different medications they currently take on a daily or as needed basis for their cancer. Medication frequency was assessed as a categorical variable.

Behavioral Characteristics. Perceived Diabetes self-efficacy was measured using a modified version of the Confidence in Diabetes Self-Care Scale (CIDS) (van der Ven et al., 2003)**.** The CIDS is a reliable and valid measure that has been used to measure diabetes specific self-efficacy in type I diabetics. The CIDS measures a person's confidence in ability to perform 20 different diabetes specific self-management behaviors. For each item participants were asked to rate on a 5 point likert scale ranging from 1, No, I am sure I cannot to 5, Yes, I am sure I can. All items are preceded with "I believe I can……". Specific items asked include: check my blood glucose at least two times daily, adjust my insulin when I am sick, and keep my blood glucose in the normal range when under stress. The CIDS has a internal consistency reliability

of .90 and a test-retest reliability coefficient of .85. The CIDS has been validated in both U.S. and Dutch populations (van der Ven et al., 2003). For this study an additional question was added addressing the patients belief that they can take their medications as prescribed in order to adapt the questionnaire to individuals with type II diabetes who are not on insulin. A total perceived self-efficacy score was developed by summing all of the items and was considered a continuous variable.

OE was measured with the OE subscale of the Multidimensional Diabetes Questionnaire (MDQ) (Talbot, Nouwen, Gingras, Gosselin, & Audet, 1997). The OE subscale consisted of 6 items which measured the patients perceptions of the effects of self-management behaviors on metabolic control and prevention of complications and has documented validity and reliability (Cronbachs alpha of .86) (Talbot, et al., 1997). All items were measured on a 10 point scale. A total OE score was developed by summing all of the items.

Depression/Anxiety was measured by using the Hospital Anxiety and Depression Scale (HADS). The HADS consisted of a total of 14 items measured on a 4 point likert scale, ranging from 0 - 3. Seven of the items screen for the presence of depression and the other 7 screen for the presence of anxiety (Snaith, 2003). Each subscale was summed individually, scores of 0 – 7 for either subscale is indicative of normal range, or not having the condition. Score of 8 – 10 indicates mild disorder, 11 – 14 moderate disorder and 15 to 21 indicates presence of severe disorder (Fossa, Dahl, & Loge, 2003). The coefficient alpha is .89 for the depression subscale and .86 for the anxiety subscale (Olsson, Mykletun, & Dahl, 2005). The HADS anxiety scale has a sensitivity of .89 and specificity of .75, the depression subscale has a sensitivity of .80 and specificity of .88 (Olsson, et al., 2005).

Diabetes Self-Management Behaviors. The Self-Care Inventory – R (SCI-R) (Weinger, Butler, Welch, & La Greca, 2005) was used to measure diabetes self-management. The SCI-R is a 15 item self-report measure which assesses patient perceptions regarding their adherence to diabetes self-care recommendations. The SCI-R measures how well individuals have followed a prescribed regimen for diabetes care over the past month. Specific items included: check blood glucose with monitor, take the correct dose of diabetes pills or insulin, take the diabetes pills or insulin at the right time, eat meals/snacks on time, exercise, and adjust insulin dosage based on glucose values, food and exercise. Individuals were asked to rate each behavior on a 5 point Likert scale, ranging from 1, never do it, to 5, always do this as recommended without fail (Weinger et al., 2005).

The SCI-R has been tested and validated in individuals with either type I and type II diabetes. The internal consistency reliability coefficient was 0.87 and had a reliability coefficient in individuals with type I diabetes of 0.84 and type 2 diabetes of 0.85. Convergent validity of the SCI-R shows a positive correlation with self-esteem and self-efficacy, and is negatively correlated with diabetes related emotional distress and anxiety (Weinger et al., 2005). The SCI-R also has demonstrated ability to respond to change (Weinger et al., 2005).

Impact of Cancer on Diabetes Self-management. The Impact cancer has on diabetes self-management was measured using a modified Illness Intrusiveness scale (Devins, 2010). The Illness Intrusiveness Scale (IIS) is a 13 item scale which asks respondents to rate the degree to which their illness interferes with their quality of life. The IIS asks respondents to rate how much their illness or its treatment interferes with aspects of an individual's life, such as diet and exercise, on a 7 point Likert scale, with 1 reflecting not very much and 7 reflecting very much

(Devins, 2010). The IIS has an internal consistency which ranges from .80 to .90, with a test-retest reliability of .80 (Devins, 2010).

The scale was modified to ask how much the patient's cancer and its treatment interfered with different aspects of their diabetes self-management, utilizing the same 7 point Likert scale. The modified scale consisted of 5 questions which addressed different aspects of diabetes self-management, diet, exercise, managing blood sugars, taking medications and self-management activities in general. The modified instrument reliability coefficient was calculated is reported in chapter 5.

Approach to Statistical Analysis

Data analysis for the quantitative portion of the study was done using PASW 18 ("PASW Statistics ", 2009). Atlas.ti ("Atlas.ti," 2009) was used to analyze the open ended question for this study. The main focus of this pilot study was to examine the relationship among individual, clinical and behavioral characteristics and diabetes self-management behaviors at baseline and at 8 weeks after starting chemotherapy. Initially the frequency distributions of descriptive variables (means, median, percentages and standard deviations) were computed. This general descriptive data was used to report socio-demographic characteristics, cancer and diabetes characteristics, and behavioral characteristics of the sample. In addition, to the frequency distribution, measures of central tendency, skewness and variability were assessed for all study variables. The use of correlations and linear regression was used to analyze the data. The following equation was used: $y_i = \beta_0 + \beta_1 x_{i1} + \beta_2 x_{i2} + \ldots\ldots\ldots + \beta_j x_{ij} + \epsilon_i$. The specific analysis plan for each aim is outlined in the following section:

Aim 1: Among patients with pre-existing diabetes who are either starting, or are currently receiving outpatient chemotherapy for a solid tumor cancer how does clinical

characteristics and behavioral characteristics relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

The Pearson-r was run between each of the independent variables and the dependent variable (diabetes self-management behaviors) in order to determine if a positive or negative relationship between these variables at baseline. Here the independent variables included clinical characteristics (symptoms, number of comorbidities, type of diabetes, diabetes severity, number of medications, cancer type, stage, type of chemo & number of cancer medications), level of depression/anxiety, self-efficacy and outcome expectancies. A linear regression model was used to determine which of the independent variables were statistically related to diabetes self-management behavior performance at baseline, while controlling for the covariates which consisted of individual characteristics of age, sex, marital status, living arrangements, race/ethnicity, and income status. The equation for this analysis was: self-management behaviors-baseline = clinical characteristics + level of depression + level of anxiety + level of self-efficacy + level of outcome expectancies + individual characteristics.

Aim 2: Among patients with pre-existing diabetes who have completed a minimum of 8 weeks of outpatient chemotherapy how does baseline clinical and behavioral characteristics, self-management behaviors for diabetes at baseline, cancer impact on diabetes and symptom burden at 8 weeks relate to the performance of diabetes self-management behaviors while controlling for individual characteristics. The Pearson-r was run between each of the independent variables and the outcome variable (diabetes self-management at 8 weeks after starting chemotherapy) to determine if there is a positive or negative relationship between these variables. Here independent variables included clinical characteristics, level of depression/anxiety, self-efficacy, outcome expectancies, baseline self-management behaviors,

and impact of cancer on diabetes self-management and symptom burden at 8 weeks. A linear regression model was used to determine which of the independent variables are statistically related to the level of diabetes self-management behaviors at 8 weeks after starting chemotherapy while controlling for the covariates of individual characteristics. The equation for this analysis was: diabetes self-management behaviors at 8 weeks = clinical characteristics+ level of depression + level of anxiety + level of self-efficacy + level of outcome expectancies + self-management behaviors at baseline + cancer impact on diabetes + symptom burden at 8 weeks + cancer impact on diabetes + individual characteristics.

In addition to the primary analysis, a sub-analysis using paired t-test was performed to assess if there were significant differences between the means of baseline and 8 week symptom severity. Cancer specific symptoms of fatigue, pain, appetite and nausea were also compared between baseline and 8 weeks. A comparison was also done between the means of baseline and 8 week diabetes self-management activities to see if there was change in relation to the performance of self-management behaviors.

*Aim 3: To identify common challenges or concerns regarding the self-management of diabetes in older adults after completing at least 8 weeks of outpatient chemotherapy***.** Specific research questions: 1) Based on your experiences over the past 8 weeks, what do you think have been some of the challenges or issues you have had to face in regards to managing your diabetes?; and 2) In general describe how your diabetes has been affected or impacted since you started undergoing chemotherapy for your cancer?

This aim was analyzed using Atlas.ti version 6 ("Atlas.ti," 2009). The responses to the single open ended question were transcribed and then uploaded in to Atlas.ti version 6 ("Atlas.ti," 2009) for analysis. Each individual transcript was read at least twice and then coded.

The transcripts were compared for similar codes, in order to identify common concerns or issues across participants. All transcripts were coded and analyzed by the study investigator. The study investigator used thematic analysis approach for coding the transcripts. During the coding process the study investigator kept a study log regarding personal reflections, analytical and theoretical decisions.

Sample size estimates – Power Analysis

A post hoc analysis was done in order to determine power. In estimating the potential power of this study, the applicant reviewed the literature in regards to reported effect sizes for the outcome variable of self-care behaviors, using the SCI-R. Two studies were identified, which reported effect sizes ranging from small (.16) (Garcia, 2008) to moderate (.37) (Wallace et al., 2009). Power calculations were done using the program G-power (Faul, 2008). Calculations were based on using a f-test for a linear model. Calculations were run using an effect size of .16, α=0.05, Power (1-β) = 0.8, which produced a required sample size of 70. The calculations were repeated using and effect size of .37, which produced a required sample size of 17.

Quality Control and Data Management

To ensure that quality and consistency of the collected data for this study the following measures were taken: **1:** Development of a procedure manual: This manual included recruitment procedures, enrollment procedures, and consent procedures and forms, all instruments and forms to be utilized in the study, approach to managing and analyzing data, interview protocols, and methods for evaluating interviews throughout the data collection period. **2:** Training and evaluation of interviewers, in case there were interviewers in addition to the study investigator for the 8 week collection times. This training included the study investigator conducting practice interviews which will be taped and evaluated to ensure that the questions and interview methods

are applied correctly. Every interview conducted at 8 weeks was tape recorded, in order to obtain and develop a transcript for the qualitative section of the study. **3:** Data management: all collected data was entered into PASW by student volunteers. A codebook was developed that linked the study variables to variable names in PASW. All interview forms will have an identification number which will correspond with the subject ID variable in PASW. Random checks will be made to ensure that data was entered completely and correctly by the study investigator. All tapes of the data obtained from responses to the open-ended question, were transcribed into a word document. This word document was uploaded into and Atlas.ti for purpose of analysis. **4:** Data collection sites were approached by the study investigator, once agreement was reached regarding their participation in the project, the study investigator provided educational training to the staff that were identifying potential participants regarding, inclusion and exclusion criteria, and study protocols. The study investigator also made periodic contacts throughout the study with the sites to assess for any problems associated with recruitment and to help problem solve, to ensure that recruitment of participants is consistent across sites. **5:** The study investigator addressed with the site coordinators any recruitment issues which arose, if it was identified that recruiters were not following protocols, the issues were discussed with them and a plan to address the issues was developed, if problems continued to occur the sites were removed from the study.

Potential Difficulties & Limitations:

It is acknowledged by the study investigator that participant recruitment could be a potential difficulty. Since, participants are not going to be consented by the sites, and will take packets home to review, complete and return to the study investigator it is possible that surveys will not be returned. The study investigator will work with the sites to ensure that packets are

being given out appropriately and will check with them weekly to see how many have been distributed in order to determine rate of return. If return rates are significantly low, the study investigator may need to consider having patients consented by the study sites and then follow up with enrolled participants by phone in order to complete the baseline survey. In addition, the study investigator acknowledges that additional sites may need to be recruited, in order to ensure that an adequate sized sample is recruited within the study period.

The study investigator met regularly with her committee to discuss issues regarding recruitment, in order to identify other recruitment strategies as necessary and to identify when additional sites may be needed. In order to control for possible attrition of subjects after the baseline survey is completed, the study investigator will mail a reminder card four weeks prior to the follow up phone survey. In addition to reminding the participant of the follow up survey, the card will also ask the patient to contact the study investigator if the previously scheduled date would need to be rescheduled.

Protection of Human Subjects

Risk to Human Subjects:

Human Subjects Involvement and Characteristics: Participants in this study included individuals 50 years of age or older who have diabetes and a recent diagnosis of cancer, who were eligible to receive chemotherapy or who were already on chemotherapy. Individuals who were cognitively impaired or unable to use a telephone were not eligible for participation in this study. Subjects were recruited from a total of 7 different cancer centers, 6 in lower Michigan and 1 in Ohio. Sites were responsible for identifying potential participants and supplying them with study information and a consent form. If a subject was willing to participate in the study they were required to return a signed consent form to the study investigator.

Sources of Materials: Upon receipt of the consent form and completed initial survey the study investigator contacted the participant to set up the 8 week telephone interviews. The initial survey obtained socio-demographic information, information regarding their diabetes and cancer treatment, level of diabetes perceived self- efficacy and questions regarding their current self-management behaviors. During the 8 week interviews questions regarding symptoms and self-management of their diabetes were asked. In addition, during the 8 week interview two open-ended questions were asked and tape recorded. The survey instruments did not include the subjects name or other identifying information. All consent forms, which had subjects names, ID numbers and contact information were kept in a locked file which only the study investigator had access too.

Potential risks: Subjects were not placed at physical or financial risk by their participation in this study. Participants could choose to withdraw from participation in this study at the time the study investigator contacted them to complete the interview. They also could elect to have the study investigator contact them at an alternate time if they were are unable to complete the questionnaire at that time. There is a potential risk for the subjects to incur stress related to answering questions and to the time it may involve.

Adequacy of Protection Against Risks

Recruitment and informed consent: Recruiters were employees of the participating cancer centers. All recruiters were trained by the study investigator in regards to the inclusion and exclusion criteria for study participants and general information regarding the purpose of the study. Once a potential participant was identified by a recruiter, they gave the patient a packet with information regarding the study, contact information for the study investigator, a consent form and stamped envelope to be used to return the signed consent form to the study

investigator. When the study investigator contacted the subject to complete the survey, she reconfirmed consent for participation.

Protection against risk: All subjects were assured by the study investigator regarding the confidentiality of all information given during the interview. They were informed that the information will not be shared in any way resulting in their identification. Data was reported as aggregate only and not individually. They were also informed that only the consent form would have any identifying data on it, and that only the study investigator had access to these forms. Subjects were given the opportunity to ask questions about the study and the process to ensure they understand any potential risk of their involvement in the study.

Women and Minorities

Women: Approximately 48% of all new cancers will occur in women (Jemal et al., 2009). Women make up approximately 50% of the population in the United States ("USA quickfacts from the US census bureau," 2009). 10.2 % of women over the age of 20 will have diabetes which is only slightly less than total estimated percentage of men with diabetes (11.2%) ("Total prevalence of diabetes and prediabetes," 2009). Based on these facts, the study investigator made all attempts to have similar percentages of women with diabetes and cancer in this study.

Minorities: African Americans make up approximately 12.8% of the population in the U.S. and 14.3 % of the population in Michigan ("USA quickfacts from the US census bureau," 2009). Asians make up approximately 2.4% of the population Michigan, were individuals of Latino or Hispanic origin make up approximately 4.0% of the population in Michigan ("USA quickfacts from the US census bureau," 2009) African American men have a 18% higher incidence rate of cancer when compared to white men (Jemal et al., 2009). African-American women have a 6% lower incidence rate for cancer when compared to white females (Jemal et al., 2009) 9.8% of

non-Hispanic whites and 14.7% of non-Hispanic blacks in the U. S. will have Diabetes. Based on these facts, the study investigator made all attempts to recruit similar percentages of minorities with diabetes and cancer into this study.

Chapter 5

Results

The primary purpose of this study was to explore the relationship between clinical and behavioral characteristics and the performance of diabetes self-management behaviors in adults 50 and older, with preexisting diabetes and undergoing chemotherapy for cancer over an 8 week time period. The secondary purpose of this study was to identify specific issues adults with diabetes who were undergoing chemotherapy experience in relation to managing their diabetes. This study sought to address the following aims:

Primary Aims:

1. Among patients with pre-existing diabetes who are either starting, or are currently receiving outpatient chemotherapy for a solid tumor cancer how does clinical characteristics associated with diabetes and cancer and behavioral characteristics relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

2. Among patients with pre-existing diabetes who have completed a minimum of 8 weeks of outpatient chemotherapy, how does baseline clinical and behavioral characteristics, baseline diabetes self-management behaviors and symptom burden after 8 weeks of chemotherapy relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

Secondary Aim:

1. To identify common challenges or concerns regarding the self-management of diabetes in older adults after completing at least 8 weeks of outpatient chemotherapy.

The following sections will present the results from this study. Sample characteristics, and descriptive analyses of each aim will be presented. In addition, reliability of study instruments, and scoring information will be presented. Interpretation and discussion of the results and implications will be presented in chapter 6.

Study Measures

Operational definitions for all study variables were provided in chapter 4. The following section will discuss the actual measurement and scoring for each variable. Reliability coefficient for each of the study instruments for this study will be presented. Reliability data for each instrument for this study can be found in tables 2 & 3.

Predictors/Covariates

Individual characteristics.

Age. Each participant reported their date of birth. Their age in years was calculated based on the date of enrollment into the study and treated as a continuous variable for analysis.

Sex. Each participant self-reported their sex as either male or female. They were scored as 1.00 for male and 2.00 for female in SPSS. Sex was treated as a categorical variable for analysis.

Household Income. Income was a self-reported variable. Participants were asked to select the total household income which best reflected them. Income was categorized into 5 different categories ranging from less than or equal to $49,999 per year to great than or equal to $200,000 per year. Income was treated as a categorical variable for analysis.

Marital Status. Each participant was asked to report their current marital status. They were to choose the category which best reflected them. Categories included never married, married, divorced/separated, widowed and living together. Marital Status was treated as a categorical variable for analysis.

Living arrangements. Individuals were asked to report their current living arrangements based on established categories. These categories were live alone, live with spouse/significant

other, live with family member other than spouse/significant other and live with non-family member.

Race. Each participant was asked to select the category which best fit their race. Categories included, Caucasian/White, African American/Black, Mexican American/Hispanic/Chicano, Native American/Alaskan and other. Race was treated as a categorical variable for analysis purposes.

Ethnicity. Each participant was asked to select the ethnicity which best fit them. Categories were Hispanic or Latino, or non-Hispanic or Latino. Ethnicity was treated as a categorical variable.

Clinical characteristics.

*Number of comorbidities***.** Participants were asked if they had specific comorbidities based on the Katz Comorbidity Index (Katz, et al., 1996). These comorbidities included hypertension, asthma, chronic lung disease other than asthma, congestive heart failure, heart attack, stroke, neurological condition, arthritis, and emotional, nervous or psychiatric problem. Participants were also asked to list any other chronic condition they currently had other than their cancer or diabetes. Each condition was coded 1.00 for yes, and 0.00 for no. For other, the study investigator reviewed what was written to ensure that they reported a chronic condition other than what had already been reported. A variable titled total other was then developed and the number of other conditions was entered. A total number of comorbidities other than diabetes and cancer was developed by summing all comorbidities and total other together. This variable was treated as a continuous variable for analysis.

Symptom Burden. The Symptom of Illness Checklist (Stowell, et al., 2009) was used to collect data on 33 different symptoms common in illness. This instrument was described in

chapter 4. This instrument is scored by individuals selecting a frequency for each symptom and an interference level. In order to develop a total symptom burden (severity) score the frequency score for each symptom was multiplied by its interference score. The total severity scores for each item were summed to create a total symptom burden score. This instrument was administered at both baseline and eight weeks. A Cronbachs alpha for this instrument for this study was determined to be .86 at both baseline and 8 weeks. This is consistent with the reported reliability of the instrument (Stowell, et al., 2009). Reliability coefficients were also calculated for the instruments subscales of frequency and interference for baseline and 8 weeks. The frequency subscale had an $\alpha = .77$ and .76 respectively, and the interference subscale had an $\alpha =$ .82 and .79 respectively.

Number of years with diabetes. Participants were asked to self-report the total number of years they had diabetes. This variable was considered a continuous variable for analysis.

Type of diabetes. Participants were asked to select if they had Type I or Type II diabetes. Type I diabetes was coded as 1.00 and type II coded as 2.00 for analysis. Diabetes type was treated as a categorical variable for purposes of analysis.

Diabetes treatment. Participants were asked to select the type of medications they were on for their diabetes. Participants could choose oral medication, insulin or oral and insulin both. Diabetes treatment type was treated as a categorical variable for purpose of analysis. Insulin was coded as a 1.00, oral medications coded as a 2.00 and both insulin and oral was coded as a 3.00.

*Total number of medications***.** Participants were asked to report the number of medications they took for their diabetes, their cancer, and their other comorbidities. The reported number of medications for each category was summed to develop a total number of medications. This variable was treated as a continuous variable for analysis.

Diabetes Severity. Diabetes severity was measured using the Diabetes Complication Index (Fincke et al., 2005). This instrument was described in chapter 4. A Cronbachs alpha was computed for this instrument for this study ($\alpha = .69$). Prior psychometrics have not been reported for this instrument. For each item participants were asked to choose yes if they had the problem and no if they did not. Items were coded as 1.00 for yes and 0.00 for no. Items for coronary artery disease (CAD), cerebrovascular disease (CVD), peripheral vascular disease (PVD), neuropathy, foot problems and eye problems were all summed to obtain a total severity score. Higher scores were indicative of having more diabetes associated complications, and were interpreted to mean greater diabetes severity. CAD, CVD, neuropathy and foot problems were all computed variables based on answers to specific questions.

CAD was determined by summing patient selected answers to blockage in blood flow to your heart, angina and myocardial infarction. The sum of 3 was considered positive for having CAD. CVD disease was computed by summing scores for questions that asked regarding if the individual had ever had a stroke or a transient ischemic attack (TIA). The sum of 1 or more was considered positive for having CVD. Neuropathy was computed by summing answers to questions which asked regarding presence of peripheral neuropathy and autonomic neuropathy. A sum of 1 or greater was positive for the presence of neuropathy. Foot problems was computed by summing answers to the questions regarding ulcers on the feet or lower legs, gangrene and amputated feet or toes. A sum of 1 or greater was positive for having foot problems.

Cancer type. Participants were asked to identify the type of cancer they had from a list of common cancers. These included breast, lung, colon, liver, pancreas, ovarian, bladder, gynecological, gastrointestinal, lymphoma and prostate. If the type of cancer they had was not on

the list, they were asked to write in their diagnosis. Cancer type was treated as a categorical variable for purposes of analysis.

*Cancer Stage***.** Participants were asked to self-report there cancer stage as either early or late. This variable was coded as 1.00 for early and 2.00 for late, and was considered a categorical variable for analysis purposes.

Length of time on chemo. The total number of chemo days was determined by computing the total number of days from their self-reported chemo start date, and the date they completed the study. This variable was reported in total days, and was treated as a continuous variable for analysis.

*Cancer impact on diabetes self-management***.** Cancer impact on diabetes self-management scale was described in chapter 4. This instrument was developed for this study, based on the illness intrusiveness scale (Devins, 2010). The instrument consisted of 5 items and scores for all 5 items were summed in order to obtain a total impact score. The Cronbachs alpha for this instrument was $\alpha = .85$ for this study. This variable was treated as a continuous variable for purposes of analysis.

Behavioral characteristics.

Diabetes self-efficacy. The Confidence in Diabetes Self-Care Scale (van der Ven, et al., 2003), was modified to measure diabetes self-efficacy in this population. This scale was described in chapter 4. The original scale had 20 items, and additional item was added which addressed the individual's belief in their ability to take medications as prescribed, in order to accommodate individuals with type II diabetes who are not on insulin. A internal consistency reliability coefficient for this single concept instrument was $\alpha = .86$ for this study. This alpha is slightly lower than the reported reliability of $\alpha=.90$.

Scoring of the Confidence in Diabetes Self-Care Scale was done by transforming all total scores to a 0 – 100 scale. This was done by taking the patients raw score minus the lowest possible score and then dividing by the possible score range, and then multiplying by 100 (van der Ven, et al., 2003). The patient's raw score was determined by summing all the items together to create a total diabetes self-efficacy score. This variable was treated as a continuous variable for analysis.

Outcome expectancies. Diabetes outcome expectancies was measured using the outcome expectancies subscale of the multidimensional diabetes questionnaire. This instrument was discussed in chapter 4. The original survey utilized a 0 – 100 scale. For this study a 0 -10 scale was utilized, and then the total raw score was converted to a 0 – 100 range, utilizing the same method described for the confidence in diabetes self-care scale. The Cronbachs alpha for this scale was determined to be $\alpha = .87$ for this study, which is consistent with reported reliabilities for this instrument (Talbot, et al., 1997). This variable was treated as a continuous variable for analysis.

Depression/Anxiety. Depression and anxiety was measured using the Hospital Anxiety and Depression Scale (Snaith, 2003). Information regarding this instrument was provided in chapter 4. For scoring items 1, 3, 5, 6, 8, 10, 11, and 13 were reverse coded once the questionnaire was completed and data was entered into SPSS. Total anxiety score is developed by summing items 1, 3, 5, 7, 9, 11, and 13 and a total depression score is developed by summing items, 2, 4, 6, 8, 10, 12 & 14. The Cronbachs alpha for this scale was $\alpha = .86$ for all items, and $\alpha = .81$ for the anxiety subscale and $\alpha = .69$ for the depression subscale for this study. The reliabilities obtained for this study are lower than the originally reported reliabilities for the

subscales, which are anxiety α=.89 and depression α=.86 (Snaith, 2003). This variable was treated as a continuous variable for analysis.

Dependent Variable

Diabetes self-management. Diabetes self-management was measured with the Self-care Inventory-Revised (Weinger, et al., 2005). This instrument was described in chapter 4. This instrument consisted of 15 items which measure self-care activities for diabetes, and is scored by summing all items and then converting the raw score to a score ranging from 0 – 100. This was done by taking the patients raw score and subtracting the lowest possible score, and then dividing by the score range, which is then multiplied by 100

Table 2:

Internal consistency reliability statistics for study instruments at baseline

Instrument	N of Items	μ	Variance	sd	α
Symptoms of Illness Checklist*	60	31.53	410.39	20.26	.86
Symptom Frequency subscale	30	23.09	203.18	14.25	.77
Symptom Interference subscale	30	8.29	48.76	6.98	.82
Diabetes Complications Index**	13	1.79	4.17	2.04	.69
Confidence in Diabetes Self-Care Scale	21	88.03	173.60	13.17	.86
Outcomes Expectancies Scale	6	55.52	58.32	7.64	.87
Hospital Anxiety and Depression Scale	14	25.18	55.90	7.47	.86
Anxiety Subscale	7	12.94	19.99	4.47	.81
Depression Subscale	7	11.78	11.67	3.41	.69
Self-care Inventory Revised	15	43.97	97.48	9.87	.74

*The following items were removed due to zero variance: cold sores frequency and interference, menstrual problems frequency and interference.
**Item for Stroke was removed due to zero variance

(Weinger, et al., 2005). The patient's raw score was determined by summing all the items together to create a total self care score. This variable was treated as a continuous variable for analysis. An internal consistency reliability coefficient was calculated for this instrument, and

was determined to have a $\alpha = 74$ at baseline and .80 at the 8 week interval. Both the baseline and 8 week reliability scores obtained were lower than those originally reported for this instrument (α=.87).

Table 3:

Internal consistency reliability statistics for study instruments at 8 weeks

Instrument	N of Items	μ	Variance	sd	α
Symptoms of Illness Checklist*	58	37.37	452.62	21.27	.87
Symptom Frequency subscale	31	28.11	224.25	14.98	.76
Symptom Interference subscale	27	9.26	53.28	7.30	.79
Cancer Impact on Diabetes Scale	5	16.81	80.23	8.96	.85
Self-care Inventory Revised**	14	40.59	127.79	11.30	.80

*The following items were removed due to zero variance: Menstrual problems frequency and interference, rash, sinus, cold sore and lymph interference
**The following item was removed due to zero variance: checking ketones

Sample

Once IRB approval was obtained from MSU and the other sites for this study (see appendix for IRB approval letters) a total of 34 patients who met inclusion criteria were enrolled in this study, once IRB approval was received from Michigan State University, and the individual cancer centers (see appendix for approval letters). A total of 55 baseline surveys were distributed. Out of those, 35 were returned (64%). Of those who returned there baseline surveys, 29 (85%) subjects completed the 8 week follow up survey. Reasons for noncompletion included: 2 deceased, 1 unable to complete due to placement into an extended care facility, and two individuals did not respond to requests for follow up. See figure 3 for consort table.
Of the participants who were eligible and enrolled in the study, 52.9% (n=18) were female, 61.8% (n=21) were married. The majority were Caucasian (85.3%, n= 28), most had some college education or completed college (66.5%, n= 26). The majority had type II diabetes

(94.1%, n= 32), and late stage cancer (61.8%, n= 22). The most common cancers were breast (29.4%, n=10), pancreas (14.7%, n= 5) and lung (11.8%, n=4). The majority was receiving outpatient IV chemotherapy (55.9%, n=19), 29.4% (n= 10) were receiving both IV chemo and radiation.

Of the participants who completed the study, 58.6% (n=17) were female, 69 % (n= 20) were married, and most had some college or completed college (71.4%, n= 21). The majority were Caucasian (79.3%, n= 23), had type II diabetes (93.1%, n= 27), late stage cancer (65.5%, n= 19) and were receiving IV chemotherapy (58.6%, n= 17). See tables 4 & 5 below for further sample information.

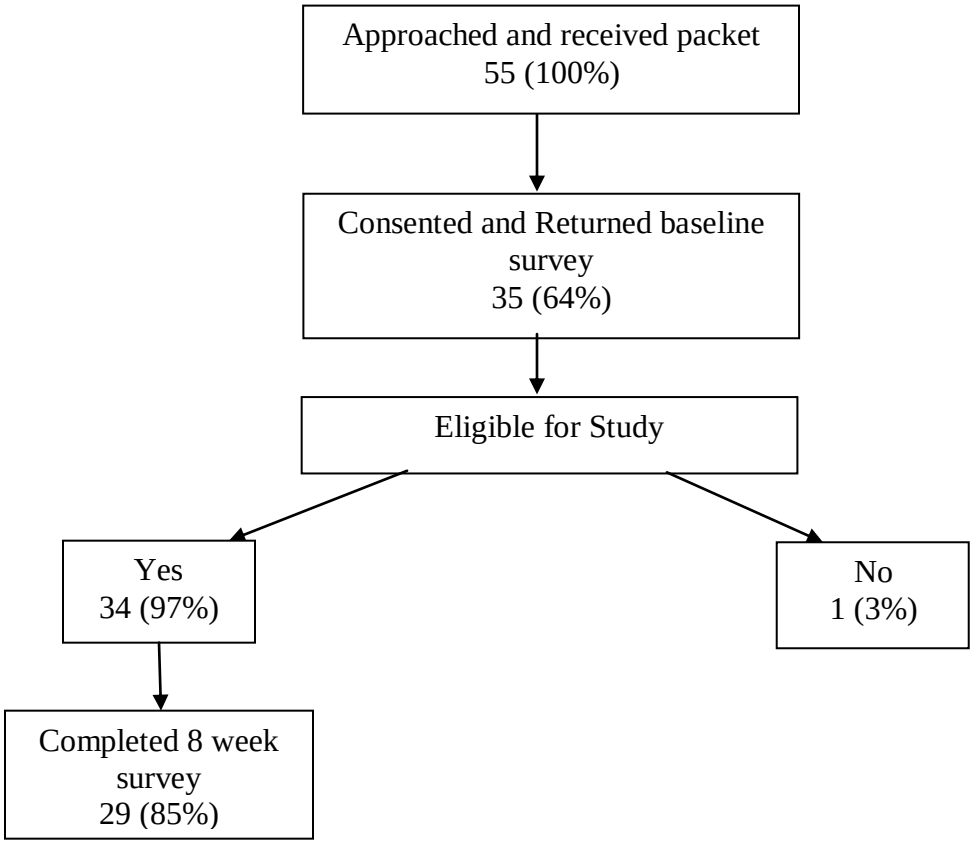

Figure 3: Consort table of study flow and enrollment indicating number approached, enrolled and completion of study

Figures 4, 5 & 6, present sample distribution information for the outcome variable of diabetes self-management behaviors, and for the behavioral characteristic of diabetes self-efficacy in the form of a histogram. For diabetes self-management behaviors at baseline the skewness was .108, and at 8 weeks was .202. The Kurtosis was -1.066 at baseline and -.173 at 8 weeks. Diabetes self-efficacy had a skewness of -.753 and kurtosis of .957.

Table 4:

Sample characteristics, N and % for categorical variables at baseline and 8 weeks:

		Baseline		8 Weeks	
Variable		N	%	N	%
Sex					
	Male	16	47.1	12	41.4
	Female	18	52.9	17	58.6
Race					
	Caucasian/White	28	82.4	23	79.3
	African American/Black	5	14.7	5	17.2
	Mexican American/Hispanic Chicano	1	2.9	1	3.4
Ethnicity					
	Hispanic or Latino	1	2.9	1	3.4
	Not Hispanic or Latino	33	97.1	28	96.6
Education Level					
	No formal education or completed grade school	1	2.9	1	3.4
	Some high school	1	2.9	1	3.4
	Completed high school	6	17.6	6	20.7
	Some college or technical training	15	44.1	12	41.4
	Complete college	11	32.4	9	31.0
Marital Status	Never Married	3	8.8	3	10.3
	Married	21	61.8	20	69
	Divorced/Separated	4	11.8	2	6.9
	Widowed	5	14.7	4	13.8
	Living Together	1	2.9	0	0.0
Living Arrangements	Live Alone	4	11.8	3	10.3
	Live with spouse/significant other	22	64.7	21	72.4
	Family member other than spouse/significant other	7	20.6	5	17.2
	Non-family member	1	2.9	0	0

Table 4: Continued

Sample characteristics, N and % for categorical variables at baseline and 8 weeks:

Variable		Baseline N	Baseline %	8 weeks N	8 weeks %
Household income	≤ $49,999	17	50.0	15	51.7
	$50,000 – $99,999	11	32.4	8	27.6
	$100,000 – $149,999	1	2.9	1	3.4
	$150,000 – $199,999	1	2.9	1	3.4
Type of Diabetes:	Type I	2	5.9	2	6.9
	Type II	32	94.1	27	93.1
Diabetes Medication Type	Insulin	9	26.5	5	17.2
	Oral	21	61.8	20	69.0
	Insulin & Oral	4	11.8	4	13.8
Cancer type	Breast	10	29.4	10	34.5
	Colon	2	5.9	2	6.9
	Lung	4	11.8	4	13.8
	Liver	2	5.9	1	3.4
	Gynecological	1	2.9		
	Gastrointestinal	1	2.9	1	3.4
	Pancreas	5	14.7	4	13.8
	Lymphoma	2	5.9		
	Other	7	20.6	7	24.1
Cancer Stage	Early	12	35.3	10	34.5
	Late	22	64.7	19	65.5
Cancer Treatment Type	IV Chemotherapy	19	55.9	17	58.6
	Oral Chemotherapy	1	2.9	1	3.4
	IV & Oral Chemotherapy	1	2.9	1	3.4
	IV Chemotherapy & Radiation	10	29.4	9	31.0
	IV, Oral Chemotherapy & Radiation	1	2.9		
	Other	2	5.9	1	3.4

Table 5:

Sample characteristics, N, μ, & sd for continuous variables at baseline and 8 weeks

	Baseline					8 weeks				
Variable	n	min	max	ū	sd	n	min	max	ū	Sd
Age*	34	50	92	64.88	10.14	29	50	92	65.31	9.68
Number of years with Diabetes*	34	1.00	20.00	9.04	5.11	29	1.00	20.00	8.5	4.72
Total number of Comorbidities other than Diabetes*	34	0.0	5.0	2.67	1.55	29	0.0	5.0	2.75	1.59
Diabetes Severity Score*	34	0.0	4.00	1.26	1.30	29	0.0	4.0	1.27	1.29
Symptom Burden**	34	0.0	78.00	24.62	21.09	29	0.0	116.0	28.41	25.38
Total number of chemotherapy days***						29	50	288	124.17	63.66
Total number of medications*	34	2.00	21.00	10.14	5.08	29	3.00	21.00	10.68	5.16
Diabetes Self-efficacy*	34	41.38	100.00	81.14	13.45	29	33.33	100.00	77.72	15.58
Diabetes Outcome Expectancies*	34	27.78	100.00	91.83	13.95	29	27.78	100.00	90.93	14.74
Anxiety Level*	34	7.00	24.00	13.26	5.03	29	7.00	24.00	13.37	5.07
Depression Level*	34	7.00	20.00	11.76	3.36	29	7.00	20.00	11.79	3.36
Cancer Impact on Diabetes Self-management***						29	5.00	35.00	16.03	8.57
Diabetes Self-care Score**	34	26.56	81.25	51.79	14.98	29	15.63	81.25	47.73	15.69

*Data collected at baseline only
**Data collected at baseline and 8 weeks
***Data collected at 8 weeks only

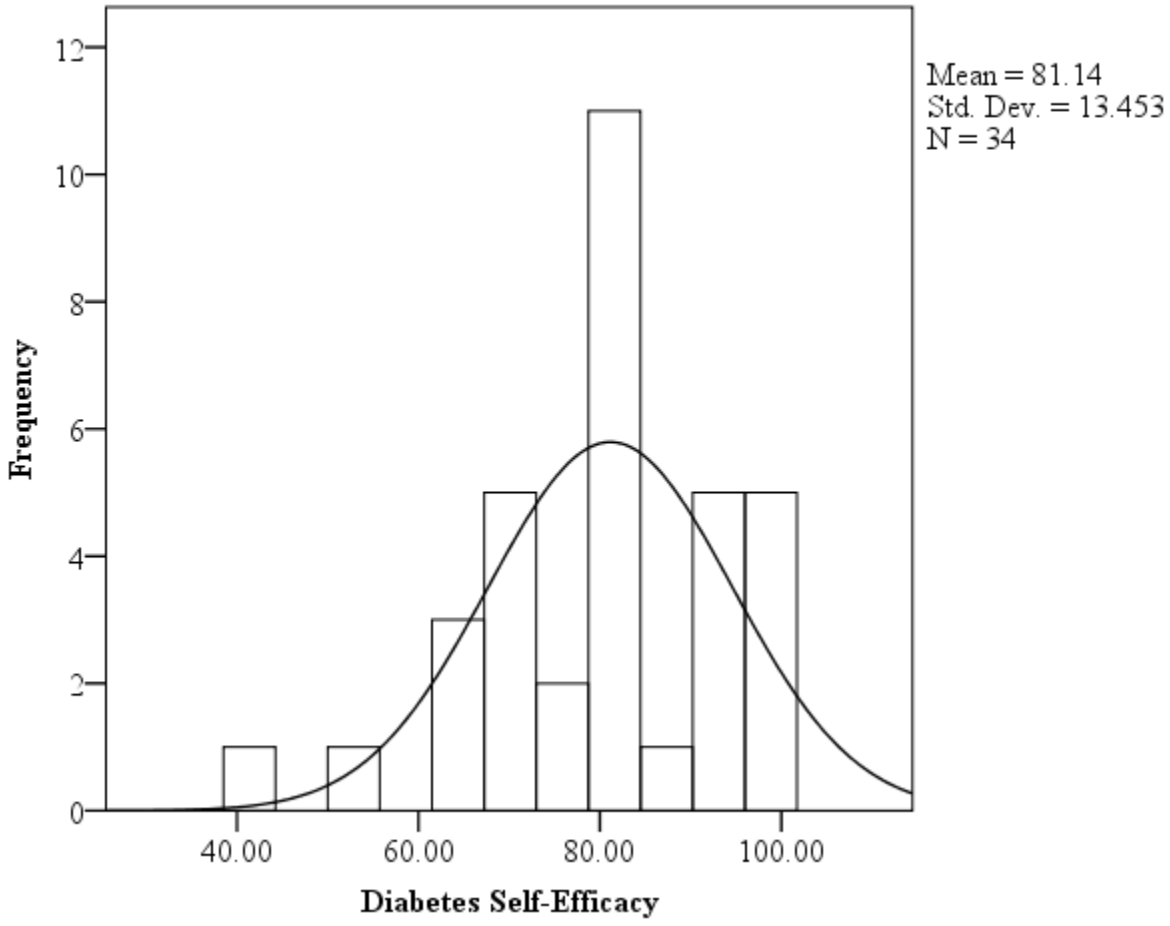

Figure 4: Histogram showing distribution of diabetes self-efficacy measure

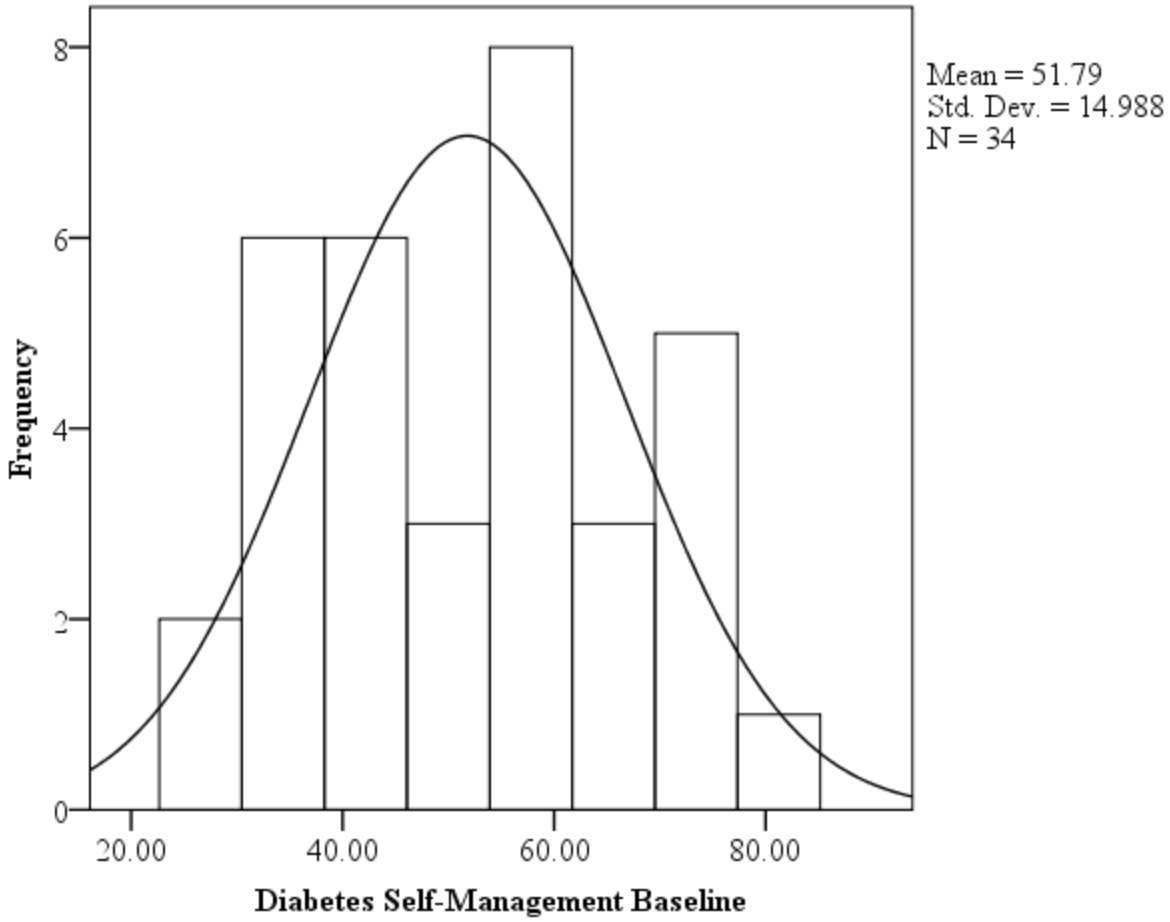

Figure 5: Histogram showing distribution of diabetes self-management measure at baseline

Results and Analysis

Aim 1. Among patients with pre-existing diabetes who are either starting, or are currently receiving outpatient chemotherapy for a solid tumor cancer how does clinical characteristics associated with diabetes and cancer and behavioral characteristics relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

Correlation analysis was utilized to determine if specific individual, clinical and behavioral characteristics were either positively or negatively related to the performance of diabetes self-

management behaviors at baseline (see tables 6, 7, 8 for correlation results). Age, DSE and number of years with diabetes were all positively correlated with the performance of self-management behaviors at baseline. As age, level of DSE and years with diabetes increased so did the performance of diabetes self-management behaviors.

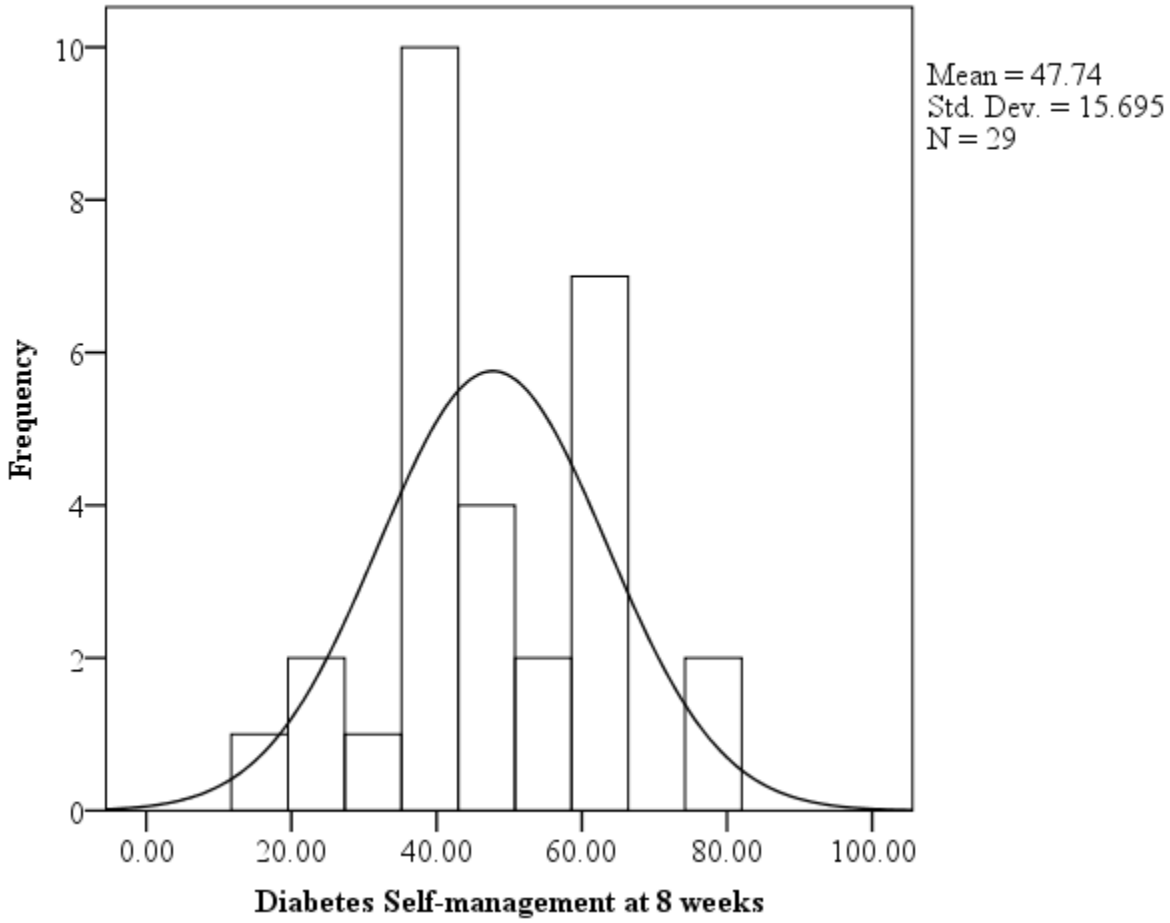

Figure 6: Histogram showing distribution of diabetes self-management measure at 8 weeks

Table 6

Correlation estimates of individual characteristics and baseline diabetes self-management behaviors (N=34)

		Sex	Age	Education Level	Race	Ethnicity	Marital Status	Living Arrangements	Baseline Diabetes Self-Management
Sex	r	1	-.289	-.063	.162	.185	.037	-.059	-.297
Age	r		1	.021	-.222	.127	.108	-.073	**.440***
Education Level	r			1	-.332	.000	-.066	-.097	.415
Race	r				1	**-.662***	-.191	-.003	-.165
Ethnicity	r					1	.076	.040	.058
Marital Status	r						1	**.382***	.125
Living Arrangements	r							1	-.172
Baseline Diabetes Self-Management	r								1

*p < .05

A linear regression model was also run at baseline to assess for possible significant predictors of diabetes self-management at baseline. In order to run this model, variables were blocked by characteristic type, individual, clinical and behavioral, and backward regression was utilized. A total of 19 iterations were completed before the final model was achieved. The final model had a R=.705, R square = .497, R square change of -.006, F= 14.84 with a p=.000. The adjusted R square for the final model was .46, indicating that the model explained approximately 46% of the variance. The initial model had an R = .792 and R square of .628. Diabetes self-

Table 7

Correlation estimates of clinical characteristics and baseline diabetes self-management behaviors (n=34)

		Diabetes Type	Diabetes Medication	Diabetes Years	Diabetes Severity	Number of comorbidities	Symptom Severity	Cancer Type	Cancer Stage	Cancer Treatment	Number of medications	Baseline Diabetes SM
Diabetes Type	r	1	.147	-.166	.040	.184	.003	.066	.077	-.010	-.056	.004
Diabetes Medication	r		1	**-.431***	-.074	.003	.228	.001	.332	.139	.173	-.198
Diabetes Years	r			1	.327	.107	-.155	-.205	-.135.	.128	.106	**.402***
Diabetes Severity	r				1	**.428***	**.459***	-.162	.117	-.013	.244	.349
Number of Comorbidities	r					1	.124	**-.441***	.260	-.152	**.583***	.211
Symptom Severity	r						1	-.168	.201	.113	.137	-.176
Cancer Type	r							1	-.125	.045	-.058	.083
Cancer Stage	r								1	.131	.062	.077
Cancer Treatment	r									1	-.155	-.109
Number of medications	r										1	.070
Baseline Diabetes SM	r											1

*p <.05

Table 8

Correlation estimates of behavioral characteristics and baseline diabetes self-management behaviors (N=34)

		Diabetes Self-Efficacy	Outcome expectancies	Anxiety	Depression	Baseline Diabetes Self-Management
Diabetes Self-Efficacy	r	1	**.382***	-.238	-.128	**.540***
Outcome Expectancies	r		1	-.114	-.210	.274
Anxiety	r			1	**.547***	-.114
Depression	r				1	-.137
Baseline Diabetes Self-Management	r					1

*bolded items indicate statistically significant correlations

efficacy and age were noted to be significant predictors of diabetes self-management behaviors at baseline (see table 9 for regression coefficients). Individuals with higher levels of diabetes self-efficacy and older age were more likely to perform self-management behaviors than those who were younger with lower levels of self-efficacy.

Table 9

Coefficients for final linear regression model indicating significant predictors of diabetes self-management at baseline

	b	Std. error	Standardized b	t	p
Constant	-38.911	16.82		-2.31	.028
Diabetes Self-Efficacy	.581	.144	.523	4.04	.000
Age	.67	.191	.452	3.49	.002

Aim 2. Among patients with pre-existing diabetes who have completed a minimum of 8 weeks of outpatient chemotherapy, how does baseline clinical and behavioral characteristics, baseline diabetes self-management behaviors and symptom burden after 8 weeks of

chemotherapy relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

Correlations analysis was utilized to determine if any predictors were positively or negatively correlated with diabetes self-management behaviors at 8 weeks. A linear regression model was run to determine what predictors contributed significantly to the performance of self-management behaviors at eight weeks while controlling for baseline self-management. Tables 10, 11 and 12 present the results of the correlation analysis.

At eight weeks none of the baseline individual characteristics were found to be significantly correlated with performance of self-management behaviors at eight weeks. The baseline clinical characteristics of number of years with diabetes and level of diabetes severity were significantly correlated with the performance of self-management behaviors at 8 weeks. Behavioral characteristics found to be significantly correlated with self-management behaviors at 8 weeks were baseline self-management behaviors and level of diabetes self-efficacy.

A linear regression model was run to determine if specific independent variables predicted performance of self-management activities at 8 weeks. A total of 15 iterations were completed before the final model was achieved. The final model had a R = .939, R square = .882, R square change = -009, F = 17.831, and p = .000. The adjusted R square was .83, the model accounted for 83% of the variance. The first model had a R = .989 and a R square = .977. Baseline self-management, number of years with diabetes, total number

Table 10

Correlation estimates of baseline individual characteristics and 8 week diabetes self-management behaviors (n= 29)

		Sex	Age	Education Level	Race	Ethnicity	Marital Status	Living Arrangements	8 week Diabetes Self-Management
Sex	r	1	-.306	-.059	.125	.225	.334	.111	-.081
Age	r		1	.024	-.272	.151	-.040	-.092	.128
Education Level	r			1	-.317	-.013	-.195	-.261	.036
Race	r				1	**-.662***	-.142	.068	.112
Ethnicity	r					1	.056	.025	.-.219
Marital Status	r						1	.285	.262
Living Arrangements	r							1	-.149
8 week Diabetes Self-Management	r								1

*p<.05

of comorbidities and ethnicity were all noted to be significant (p<.05) predictors of performance of self-management behaviors at 8 weeks (see Table 13 for regression coefficients).

Additional Analysis

In order to assess if cancer and its treatment had an impact on the performance of diabetes self-management behaviors, and to assess if the patients symptom burden significantly changed from baseline to 8 weeks, a paired t-test was utilized to compare the means of items that were collected both at baseline and 8 weeks. There were no significant differences found between baseline and 8 week means for total symptom severity (baseline $\mu = 23.37$, sd = 21.86, 8 week $\mu = 28.52$, sd = 26.17). Further analysis was done comparing symptom severity means at baseline and 8 weeks for cancer specific symptoms: pain, fatigue, nausea and appetite. No significant differences were found. For this sub-analysis pain was the combined severity scores

Table 11

Correlation estimates of baseline clinical characteristics, 8 week symptom severity, 8 week cancer impact on diabetes and 8 week diabetes self-management behaviors (n= 29)

		DM Type	DM Meds	DM Years	TDSS	# Co-morbids	Baseline TSSS	8wk TSSS	CA Type	CA Stage	CA treatment	# chemodays	# medications	CIDS	8 wk DM SM
DM type	r	1	.23	-.23	.04	.21	-.00	**-.38***	.05	.09	-.05	.26	-.04	-.21	-.04
DM Meds	r		1	**-.38***	-.09	-.01	.29	.19	.12	**.48***	.35	-.17	-.13	.19	-.20
DM years	r			1	.34	.15	-.09	.26	-.32	-.18	-.12	.23	.27	.14	**.60***
DM Severity	r				1	**.45***	**.55***	**.38***	-.23	.29	.11	-.13	.25	.25	**.43***
# of comorbids	r					1	.12	.19	**-.46**	.322	-.06	.10	**.63***	.07	.36
TSSS	r						1	**.63***	-.19	.24	.25	-.09	.15	.36	.13
8 week TSSS	r							1	-.28	.07	**.41***	-.17	.26	**.48***	.25
CA type	r								1	-.13	.03	-.09	-.09	-.31	-.13
CA stage	r									1	.09	.07	.06	.26	.06
CA Treatment	r										1	-.17	.05	-.19	-.24
# chemodays	r											1	-.00	-.21	.19
# Medications	r												1	-.02	.34
CIDS	r													1	.17
8wk DM SM	r														1

*p < .05

DM = Diabetes, TDSS = Total Diabetes Severity, TSSS = Total symptom severity, CA= Cancer, CIDS = Cancer Impact on Diabetes, SM = Self-management behaviors

Table 12

Correlation estimates of baseline behavioral characteristics and 8 week diabetes self-management behaviors

		Diabetes Self-Efficacy	Outcome expectancies	Anxiety	Depression	Baseline Diabetes Self-Management	8 week diabetes self-management
Diabetes Self-Efficacy	r	1	.286	-.172	-.046	**.655***	**.614***
Outcome Expectancies	r		1	-.028	-.135	.282	.119
Anxiety	r			1	**.550***	-.125	-.134
Depression	r				1	-.022	-.165
Baseline Diabetes Self-Management	r					1	**.726***
8 week Diabetes Self-Management	r						1

*p < .05

Table 13

Coefficients for final linear regression model indicating significant predictors of diabetes self-management at 8 weeks

	b	Std. error	Standardized b	t	p
Constant	81.52	16.66		4.89	**.000**
Ethnicity	-39.15	6.66	-.471	-.5872	**.000**
Years with Diabetes	1.26	.28	.37	4.50	**.000**
Number of Comorbidities	3.59	.76	.37	4.69	**.000**
Baseline DM Self-management behaviors	.513	.081	.502	6.29	**.000**
Diabetes Self-efficacy	.072	.134	.061	.538	.597
Diabetes Outcome Expectancies	-.071	0168	-.039	-.425	.676
Anxiety	-.287	.321	-.094	-.894	.382
Depression	.111	.540	.024	.206	.839

*bolded items represent those found to be significant

Table 14

Baseline and 8 weeks means and standard deviations for cancer specific symptoms

Symptom	N	μ	sd
Fatigue Severity	29	4.48	.73
Fatigue Severity 8 weeks		4.69	.78
Appetite	29	1.44	2.57
Appetite 8 weeks		2.03	3.06
Nausea	29	.58	1.68
Nausea 8 weeks		1.76	3.35
Pain	29	7.89	9.16
Pain 8 weeks		6.03	8.55

Table 15

Paired t-test for Symptom Severity and Diabetes self-management at baseline and 8 weeks (n=29)

	Paired differences			
Paired Variables	μ	sd	t	p
Symptom Severity Baseline Symptom Severity 8 weeks	-4.21	20.61	-.109	.281
Diabetes Self-Management Baseline Diabetes Self-Management 8 weeks	5.71	11.61	2.65	.013

backpain, abdominal pain, muscle aches and joint pain. The symptom inventory used for this study did not ask a general pain question. Even though there were not significant differences, it was noted that individuals had higher means for nausea, appetite, and fatigue at 8 weeks when compared to baseline, indicating that these symptoms had increased in severity. Overall individuals had a lower mean score for pain, indicating that they experienced less pain at 8 weeks. See table 14.

There were significant differences ($p = .013$) in regards to the overall performance of diabetes self-management behaviors (baseline $\mu = 51.40$, $sd = 16.01$, 8 week $\mu = 45.69$, $sd = 17.47$), indicating patients performed less activities to manage their diabetes after a minimum of 8 weeks of chemotherapy, then they did at baseline. (See Table 15)

In order to assess if there were specific self-management behaviors that were performed either more or less after 8 weeks of chemotherapy, a paired t-test was done to compare each of the items on the self-care inventory. There were significant differences between baseline and 8 week measures for certain specific self-care activities. These items included eating meals and snacks on time (baseline μ = 3.96, sd =.90, 8 week μ = 3.41, sd = 1.11), treating low blood glucose with carbohydrates (baseline μ=2.34, sd =2.07, 8 week μ=1.34, sd 1.95) and exercise (baseline μ=2.86, sd=1.06 and 8 week μ=2.41, sd=1.08). At 8 weeks participants were less likely to eat on time and less likely to exercise. The significant difference in treating low blood sugar maybe a reflection of how the form is scored, for if an individual did not have a low blood sugar in the 2 weeks prior to completing the form, they item was scored as 0. (See Table 16)

Table 16

Paired t –test for specific paired self-management items at baseline and 8 weeks (n=29)

	Paired differences			
Paired baseline & 8 week variable	μ	sd	t	p
Check blood glucose	-.03	1.05	-.17	.86
Record blood glucose	-.00	1.28	.00	1.00
Check ketones	.34	1.08	1.72	.09
Take correct dose of pills or insulin	.21	.98	1.14	.26
Take pills or insulin at right time	.14	1.03	.72	.47
Eat correct food portions	.31	1.00	1.67	.11
Eat meals/snacks on time	.55	1.02	2.91	**.007**
Keep food records	.10	1.18	.47	.64
Read food labels	-.17	1.28	-.72	.47
Treat low blood glucose with carbohydrates	1.00	2.36	2.28	**.030**
Carry quick acting sugar	.103	1.52	.37	.72
Come in for clinic appointments	.48	2.99	.87	.39
Wear medic alert ID	.14	.92	.81	.42
Exercise	.44	1.05	2.28	**.030**
Adjust insulin dosage	.03	1.21	.15	.879

*bolded items represent items which were statistically significant

Aim 3: To identify common challenges or concerns regarding the self-management of diabetes in older adults after completing at least 8 weeks of outpatient chemotherapy.

Thematic analysis was done to analyze the transcribed tapes in order to identify common themes. Participants were asked two open-ended questions asking them to discuss the challenges and issues regarding taking care of their diabetes while undergoing chemotherapy, and how they felt their diabetes was impacted overall by their cancer treatment. A data driven approach to analyzing the data was utilized. In using this method, raw data is examined for codes and themes across subjects. The investigator draws upon their thoughts, ideas, perceptions and knowledge of prior theories and research in the development of themes (Devins, 2010). During the analysis of the transcribed tapes, the investigator utilized reflexivity regarding preconceived ideas, feelings and emotions that may have impacted analysis by keeping memos of these thoughts and others that may have influenced the coding of the transcripts, as well as reasons for changing or merging a particular code.

Three themes were identified during analysis of the tapes: self-management issues, health issues and prioritization. Table 17 provides a definition for each theme and the indicators (a description of when the theme occurs). The theme of self-management issues included issues

Table 17

Themes with definitions and indicators:

Theme	Definition	Indicators
Self-management issues	Specific diabetes self-management behaviors which may be negatively or positively impacted by cancer and/or cancer treatment	Exercise impact, Diet Management, Medicine Management, Glucose monitoring
Health Issues	Positive or negative factors which can impact an individual's overall health while undergoing treatment for cancer	Glycemic/blood sugar issues, symptom issues, no reported impact
Prioritization	Factors which influence or impact how an individual will care for their diabetes while undergoing cancer treatment	Provider influence, personal choice, need for help

related to several specific diabetes self-management behaviors, exercise, diet, medicine management and glucose monitoring. The impact chemotherapy had on exercise was noted to be negative. As noted by the following quotes: "not able to exercise like I usually would be able to. Ya know, if you're tired, you're not going to do very much" and "because of tiredness, I am not able, or willing to exercise as much as I did before the chemo and surgery and treatment." Several individuals noted a negative impact on their diets as well: "When I do eat my blood sugar spikes to 400 -500 so then I don't want to eat so I just drink a lot of fluids"; "Challenge is my diet, um because during the cancer, you want to eat comfort foods, and most comfort foods are really not diabetic-friendly" and "No appetite, you don't have an appetite so you wait, deliberately wait and eat when you're hungry."

A few individuals reported challenges and changes in how they manage their diabetic medications in order to achieve better glycemic control. "Using a sliding scale for insulin was a challenge", and "The challenges were to become more, um efficient and um more regular about checking sugars and managing whatever medication need to be given according to the blood sugar level".

Glucose monitoring was another area noted by individuals that changed due to their cancer and its treatment. "I started taking my readings before every meal and every morning and every night. So I was taking it 5 times a day when I first started out. And I was only taking it once before" and "Diabetes is easily managed if I monitor my numbers".

The second theme identified was health issues associated with the cancer and its treatment. Many individuals reported issues with glycemic control while receiving chemotherapy. Symptoms were also frequently reported as a side-effect of the chemotherapy. A few individuals did not feel that the cancer and its treatment had any impact on their diabetes.

Individuals who expressed issues with glycemic control, manly reported issues with elevated blood sugars and inability to have consistency in their blood glucose readings: "The numbers tend to bounce around an awful lot….I can be 300 one night and then 140", "I never know what it's going to be. It's always high and I worry about I being so high that I am going to go into a coma" and the chemotherapy itself, Taxol in particular, would push sugar up over 200 the days that I would have it".

Symptoms were also frequently reported as common issues which occurred while undergoing treatment for chemotherapy. "So yucky meaning you feel like you don't have any energy or sick all the time." "I'd say the biggest thing is the way it's affected the appetite. You know, where a lot of things didn't roll off on the taste and then you start eating and it's like you hit a wall and its, you know, I can't eat anymore," and "chemo throws everything out of wack. It makes me light headed, or mostly tired. Loss of appetite, loss of hair, ups the stress level".

A few individuals reported no impact on their diabetes or health while receiving treatment. "I've had no problems at all. Chemo has had almost no impact. I took my pills this morning and I had my cereal this morning that I like, but it's pretty acceptable. I would say that it's had very little impact," and "I haven't had bad side effects from chemo, so I have been able to eat normally. I have remained active, and the chemo really hasn't gotten me down."

The third theme identified was prioritization, this theme included positive and negative issues related to provider influence, need for help and personal choice. Provider influence was noted to be both positive and negative. "my family doctor sent me to an endocrinologist and she's been trying to get it under control" and "He just said chemo drugs usually interfere and cause, you know, your diabetes to go all over,…was comfortable waiting till I was done with chemo, as long as the random ones weren't going very high"

Individuals were also noted to be making personal choices about the management of their diabetes while they were undergoing treatment for their cancer. "I am really conflicted and I am pretty much putting the diabetes on the back burner, I mean I watch it but I am focusing on what I should do for the cancer right now" and "I haven't given up on my diabetes because the whole time up until now, making sure that I am doing the right thing and my diabetes isn't going to be affected by my cancer….. I made up my mind that one was as important as the other." One individual reported help from their caregiver in order to continue to manage their diabetes, as noted by the following statement from the caregiver "He hasn't been able to give it (insulin) to himself like he used to, I do the work."

Through the use of thematic analysis, several themes and issues were identified. Overall the issues identified had a negative impact on diabetes self-management. Further discussion of these themes and how they may link to some of the quantitative results will be explored and discussed in chapter 6.

Power:

A post hoc analysis utilizing the program G-power (Faul, 2008), in order to determine the studies power. This analysis was run for the matched pair analysis (paired t-test) and for the linear regression model at 8 weeks. The paired t-test analysis revealed a effect size of .30, and a power (1-β err prob) of .46. The linear regression model revealed a effect size of .88 and a power (1-β err prob) of .99.

Summary:

This chapter presented the results from both the quantitative and qualitative analysis. Based on the results, cancer and its treatment can have an impact on the management of diabetes in older adults. Level of self-management behaviors which are recommended to be performed

daily such as monitoring blood sugars, diet and exercise were found to be significantly different between baseline and after being on chemotherapy for at least 8 weeks. Clinical factors such as symptom severity, years with diabetes, number of comorbidities and number of medications all may impact the continued management of diabetes in older adults who are receiving chemotherapy. Individuals with diabetes express issues with glycemic control, as well as the ability to follow diet and exercise regimens while undergoing chemotherapy. Further interpretation and discussion of these results will be presented in chapter 6.

Chapter 6

Discussion & Implications

This study focused on the relationship between individual, clinical and behavioral characteristics and the performance of diabetes self-management behaviors in adults 50 and older who were undergoing chemotherapy for a solid tumor cancer or lymphoma. This final chapter will present an interpretation of the results, the relationship of the results to the conceptual framework, and current research literature and limitations of the study. The implications for nursing practice, research and policy will also be presented.

Discussion of Result for Aim 1

*Aim 1***:** Among patients with pre-existing diabetes who are either starting, or are currently receiving outpatient chemotherapy for a solid tumor cancer how does clinical characteristics associated with diabetes and cancer and behavioral characteristics relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

Initially correlations where performed, and age, number of years with diabetes and level of DSE was found to be positively correlated with the performance of self-management behaviors for diabetes at baseline. A linear regression model was also performed. Age and level of self-efficacy were also found to be predictors of diabetes self-management activities at baseline in adults undergoing treatment for cancer. The older the adult, the more likely they are to perform recommended self-management activities for their diabetes. Other studies have also noted age to be a predictor of performance for diabetes self-management behaviors (Honish, Westerfield, Ashby, Momin, & Phillippi, 2006; Wen, Shepherd, & Parchman, 2004). Wen et al (2004) noted older Hispanic individuals were more likely to be compliant with diet self-management behaviors when compared to younger adults with diabetes. Honish et al (2006)

found as a person ages their level of compliance with diabetes self-management activities increases. The mean age of participants in this study was 44.71 with a sd = 9.67 (Honish, et al., 2006). It is possible that older adults, who no longer are caring for young children, and who may be retired have less demands on their time, and are better able to adhere to and perform recommended self-care behaviors than adults who may have other competing demands.

Unlike past research, this study found a positive correlation between years with diabetes and performance of diabetes self-management activities, indicating the longer an individual has diabetes the more likely they are to perform diabetes self-management behaviors. Ponzo et al (2006) noted the longer an individual had diabetes, the less likely they were to follow and perform recommend self-management activities for diabetes. Ponzo et al (2006) hypothesized that the negative relationship between years with diabetes and performance of self-management activities may be due to the development of diabetes related complications, competing comorbid conditions and more complex treatment regimens. The current study did not find a significant correlation between the number of comorbid conditions, number of medications or level of diabetes severity and the performance of diabetes self-management. Based on the findings from this study, the hypothesis proposed by Ponzo et al (2006) is not supported. This difference may be due to the difference in the populations studied. Ponzo et al (2006) studied Italian men and women who were 1st generation Italian immigrants with type II diabetes. Ponzo et al (2006) did not report how long these individuals had been in the United States, it is possible that the adjustment to a new culture also impacted their ability to perform diabetes self-management activities. Further research needs to be done in order to better understand the relationship between other comorbidities and diabetes specific clinical characteristics and the performance of diabetes self-management behaviors.

Level of DSE was also found to be significantly correlated with and predictive of performance of self-management behaviors for diabetes. As level of DSE increased, so did the performance of self-management behavior. This finding is consistent with the diabetes literature (Aljasem, Peyrot, Wissow, & Rubin, 2001; Sousa, Zauszniewski, Lea, & Davis, 2005; Williams & Bond, 2002). Higher levels of self-efficacy in individuals with diabetes has been associated with improved diet, glucose monitoring, taking of medications and exercise (Aljasem, et al., 2001; Wen, et al., 2004; Williams & Bond, 2002). Individuals with higher levels of self-efficacy will usually feel more capable and confident in their ability to perform and carry out specific activities. Individuals with diabetes with higher levels of diabetes self-efficacy when face with a competing condition such as cancer, may still feel they are capable and have the confidence to manage their diabetes.

Based on the findings for Aim 1, adults who have preexisting diabetes who are older, have higher levels of DSE and have had diabetes longer are more likely to perform diabetes self-management behaviors at baseline, or early in their treatment with chemotherapy. Nurses and other healthcare providers who are caring for individuals with diabetes and cancer who are or will be receiving chemotherapy need to understand this relationship in order to assist patients in caring for both of these disorders. Patients who have lower levels of DSE or who have not had diabetes longer may need extra support or assistance early in their treatment process in order to ensure they continue to follow self-management recommendations for their diabetes.

Discussion Results for Aim 2

Aim 2: Among patients with pre-existing diabetes who have completed a minimum of 8 weeks of outpatient chemotherapy, how does baseline clinical and behavioral characteristics, baseline diabetes self-management behaviors and symptom burden after 8 weeks of

chemotherapy relate to the performance of diabetes self-management behaviors while controlling for individual characteristics.

A correlation analysis and linear regression model were performed to determine the relationship between individual, clinical and behavioral characteristics and diabetes self-management behaviors at 8 weeks. Unlike the baseline model, age was not found to be correlated with, or predictive of self-management behaviors. Age may be a predictor early in the chemotherapy process, as indicated by the baseline model, the longer an individual is on chemotherapy, they draw from their years of experience with diabetes and management of diabetes to help them sustain and continue to perform diabetes self-management behaviors. In addition this study only looked at individuals 50 and older; age may have been found to be predictive if younger adults were included in the study.

As with the baseline correlations, DSE was found to be positively correlated with diabetes self-management activities after 8 weeks of chemotherapy. However, DSE was not found to be predictive of the performance of self-management activities after 8 weeks of chemotherapy in the linear regression model, which differs from the baseline model. It is possible that level of DSE at baseline does not sustain self-management behaviors overtime in individuals with a competing chronic condition. Individuals with diabetes may need a self-efficacy booster intervention while undergoing chemotherapy in order to sustain DSE and possibly improve the performance of self-management behaviors at baseline. A consideration has to be given to the possibility that DSE is not what is needed to sustain performance of self-management activities in this population. It may be a more general self-efficacy, or combined self-efficacy for both cancer and diabetes in this population that would possibly be predictive of or sustain better performance diabetes self-management behaviors. It is also entirely possible

that level of self-efficacy may not have anything to do with performance of self-management behaviors in adults with competing chronic conditions. In order to determine this, further research which looks at the relationship between self-efficacy and the performance of self-management behaviors in individuals with discordant or competing chronic conditions needs to be conducted.

As with the baseline correlation results, years with diabetes continued to be positively correlated with the performance of self-management activities for diabetes at 8 weeks. In the baseline regression model, years with diabetes was not found to be predictive of the performance of diabetes self-management activities. Years with diabetes was found to be a significant predictor of the performance of diabetes self-management behaviors at 8 weeks. The longer an individual had diabetes the more likely they were to continue to perform self-management activities over time while undergoing chemotherapy. One possible explanation for this is that individuals who have had diabetes longer have had to overcome other barriers or challenges in regards to caring for their diabetes in the past and have developed a process to manage their diabetes when facing a new challenge or barrier. Individuals who have had diabetes longer may already have a support system as well as an established routine in place to assist them with managing their diabetes while undergoing chemotherapy. Individuals who have had diabetes longer do not find the effects or challenges of chemotherapy to be a barrier to the performance of diabetes self-management behaviors. Individuals, who have had diabetes longer, may also have a better understanding of the importance of maintaining and caring for their diabetes, than those who have not had diabetes as long.

At 8 weeks, the number of comorbidities an individual had, their baseline level of diabetes self-management and their ethnicity were found to be predictive of level of performance

of self-management behaviors. Level of diabetes severity was also found to be positively correlated with performance of self-management activities, which was different from the baseline data. Individuals with higher levels of diabetes severity were more likely to perform self-management behaviors after a minimum of 8 weeks of chemotherapy. Past research which has looked at the relationship between diabetes related complications and performance of self-management activities in individuals, have found a negative correlation which differs from this study. These differences may be related to how diabetes complications and severity were measured. Aljasem et al (2001) used medical exam and chart audit to determine the presence of diabetes related complications, this study utilized self-report. Individuals in this study may have misreported complications associated with their diabetes, which a medical chart audit would have clarified. It is also possible, older adults with higher diabetes severity levels are more likely to perform self-management activities while being faced with a new condition such as cancer and treatment with chemotherapy, in order to prevent further complications. In addition, individuals with whose diabetes is more severe, or who may have more diabetes related complications, are more likely to be older and have had diabetes longer.

The number of comorbidities an individual had was found to be predictive of the performance of diabetes self-management comorbidities at 8 weeks. Individuals with more comorbidities performed more diabetes self-management activities than those with lower levels. The literature has proposed that the number of comorbidities an individual has creates a barrier to self-management (Bayliss, Ellis, & Steiner, 2007). Kerr et al (2007) reported discordant or competing comorbidities are more likely to impact the self-management of diabetes in adults with multiple morbidities. It can be hypothesized that in individuals who have diabetes who are

undergoing chemotherapy, have already dealt with adjusting their self-management behaviors to accommodate the management of a new chronic condition.

Ethnicity was also found to be predictive of diabetes self-management behaviors at 8 weeks. The majority of the sample was classified as non-Hispanic or Latino, with only one participant being Hispanic or Latino. Being Hispanic or Latino was noted to be predictive of lower levels of self-management at 8 weeks. These findings are based on only one individual and cannot be generalized to the population. Ethnicity in past studies has been found to have either a positive or negative effect on overall performance of diabetes self-management behaviors (Castro, O'Tolle, Brownson, Plessel, & Schauben, 2009; Lanting et al., 2008; Sowattanangoon, Kotchabhakdi, & Petrie, 2009). Future studies need to include more diverse ethnic backgrounds as well as racial backgrounds in order to better assess the role ethnicity and race plays in regards to the performance of self-management activities in this population.

Summary

At 8 weeks the clinical characteristics of number of comorbidities and years with diabetes were found to be predictors of diabetes self-management behavior, versus the individual characteristic of age and the behavioral characteristic of DSE at baseline. DSE continue to be correlated with self-management behaviors at 8 weeks. Individuals in this study with higher levels of self-management at baseline continued to have higher levels of diabetes self-management after a minimum of 8 weeks of chemotherapy. Clinical characteristics have been hypothesized to negatively impact self-management behaviors. The findings from this study indicate individuals with more comorbidities and more years with diabetes are more likely to perform diabetes self-management behaviors, while undergoing chemotherapy. These findings do not tell us if these individuals performed diabetes self-management activities at lower levels

when compared to baseline. This study did not find cancer specific clinical characteristics to be correlated or predictive of the performance of diabetes self-management behaviors. This could be due to the fact that most patients were early in their cancer care trajectory. It is possible that cancer specific clinical characteristics later in the care trajectory could impact diabetes self-management. Further research needs to be done before we can conclude that cancer and its treatment is not predictive of the performance of diabetes self-management behaviors. This study only looked at individuals over a short period of time, and it is possible that there may be an accumulative effect related to cancer symptoms, treatment type and number of treatment days which may only be detected after a longer treatment period.

Discussion of Additional Analysis

A paired t-test was performed in order to determine if there were differences between baseline and 8 week levels of self-management behaviors and symptom burden, in order to determine if the effects of chemotherapy had an impact overtime. A significant difference was not found in relation to level of symptom burden individuals were experiencing. This may be due to the fact that individuals were already undergoing chemotherapy at the time they were enrolled in the study, new symptoms or changes in symptoms associated with their cancer and its treatment were already occurring at baseline.

In further analysis, cancer specific symptoms were compared. These symptoms included pain, appetite, nausea and fatigue. There were differences noted between the 8 week and baseline means, for these symptoms these findings were not significant. Individuals overall reported higher levels of fatigue, nausea and poorer appetite's at 8 weeks when compared to baseline. It is important to note that fatigue is also a common symptom of diabetes; it is unclear if the increase in fatigue was due to the cancer treatment, or the individual's diabetes.

Individuals reported issues with glycemic control during this time which could have also impacted the patient's level of fatigue. Further research needs to further explore the relationship between diabetes, cancer and the development of fatigue in individuals undergoing treatment.

A significant difference was found between the level of diabetes self-management activities performed at baseline and those performed at 8 weeks. Indicating chemotherapy may have an impact on an individual's ability to perform self-management behaviors overtime. Individuals overall had higher levels of diabetes self-management at baseline when compared to diabetes self-management levels at 8 weeks after starting chemotherapy. The mean score for self-management activities at baseline was 51.40 and at 8 weeks was 45.69, higher scores reflected higher levels of diabetes self-management behavior performance. This difference was determined to be significant with $p < .05$. Previous literature has noted individuals with discordant conditions may have lower self-management ability, and prioritize the self-management of one disease over the other (Kerr et al., 2007) and the symptoms of one disorder may interfere with the ability to perform self-management activities for another disorder (Bayliss, et al., 2007; Jerant, von Friederichs-Fitzwater, & Moore, 2005). Differences in levels of overall symptom severity were not found to be a factor related to the performance of diabetes self-management behaviors. Further analysis may need to be done which looks at cancer specific symptoms, only, not just all symptoms associated with illness, in order to have a better understanding of this relationship and the impact symptoms may have on the performance of diabetes self-management behaviors. The decrease in the performance of self-management activities for diabetes in this study may be due to the impact cancer related symptoms may have on the ability to follow diet and exercise programs, and how the individual may prioritize caring

for their diabetes when faced with a new discordant, complex and life threatening condition such as cancer.

Specific diabetes self-management behaviors were also found to be significantly different between baseline and 8 week time periods. These included eating meals and snacks on time, treating low blood glucose with carbohydrates and exercise. Individuals were less likely to eat meals and snacks on time and to exercise at 8 weeks when compared to baseline measures. This difference can possibly be explained by the data obtained from the open ended questions where patients reported difficulty with their diets and ability to exercise due to the side effects associated with their chemotherapy. Differences in symptom burden at baseline and 8 weeks were not detected by the paired t-test. It is possible that a difference, could have been detected if the sample size was larger, there was a difference in the number of individuals who started the study versus those who completed (N = 34 at baseline, and N = 29 at 8 weeks). A different symptom assessment tool may have been more sensitive in determining differences related to cancer specific symptoms only, versus all symptoms associated with illness. Further analysis may need to be done that looks at cancer specific symptoms such as pain, fatigue, and nausea to see if there is a specific relationship between these and the performance of specific diabetes self-management behaviors.

The treatment of low blood sugar was less likely to occur after a minimum of 8 weeks of chemotherapy, when compared to the baseline measure. As mentioned in the results section, if an individual had not incurred a low blood sugar in the 2 weeks prior to completing the final survey they were scored a 0 for that item, instead of 1 through 5. This difference is most likely due to the fact that many individuals experienced issues with hyperglycemia versus hypoglycemia during this time. Many individuals reported issues with glycemic control, when

asked about how they felt the cancer had impacted their diabetes. This will be explored further in the discussion of results for Aim 3.

Summary

This analysis indicated chemotherapy may have a negative impact on the overall performance of diabetes self-management behaviors in older adults. Specifically related to the effects chemotherapy may have on diet management and exercise. Cancer and diabetes are considered discordant disorders since they do not follow a similar disease management plan. Consistent with the literature, the discordance between two conditions can create a competition for time, attention and priority and impact the self-management of one or both of the conditions (Kerr, et al., 2007; Piette & Kerr, 2006; Proctor, Hasche, Morrow-Howell, Shumway, & Snell, 2008).

Discussion Results Aim 3:

The purpose of Aim 3 was to identify common challenges or concerns, identified by individuals with both diabetes and cancer, regarding the self-management of diabetes after completing at least 8 weeks of outpatient chemotherapy using open ended questions. Three common themes were identified in individuals with preexisting diabetes who were undergoing chemotherapy; these were self-management issues, health issues and prioritization. Self-management issues identified were impact on exercise, diet, the management of medications and the monitoring of blood glucose. Diet and exercise were both negatively impacted by the chemotherapy. Individuals acknowledged that the effects related to symptoms associated with their chemotherapy decreased their appetite, and the stress associated with dealing with cancer increased their likelihood of not eating correctly. The symptom of fatigue was often mentioned as a factor which impacted their ability to exercise regularly.

The level of prioritization of diabetes self- management was also noted to be a theme found among the participants in this study. Individuals acknowledged that taking care of and dealing with their cancer was more important than caring for their diabetes. Individuals expressed being overwhelmed and preoccupied with their cancer, which contributed to them thinking less about caring for their diabetes. This lack of prioritization may also help to explain differences between baseline and 8 week performance of self-management behaviors. Patients were also influenced by their healthcare providers in regards to how much emphasis they placed on their diabetes management. Some individuals reported they were informed by their healthcare provider to not worry about their diabetes while being treated for the cancer, for the cancer treatment will probably cause problems with their blood sugars. In conversations with various health care providers, neither oncologist nor primary care providers felt comfortable in regards to managing diabetes during treatment and/or they did not feel that the management of diabetes was important while individuals were receiving chemotherapy. This indicates a need for increased education of healthcare providers regarding the relationship between diabetes and cancer and the importance of managing both diseases simultaneously.

The majority of the patients in this study did report issues with glycemic control and frustration with not being able to control their blood sugars. Through additional side observation by the investigator it was noted that several of the patients in the study required hospitalization during this 8 week period. Approximately 23% (n= 8) of the participants required hospitalization for problems including infections and cardiac related issues. In previous studies (Barone et al., 2008; Peairs et al., 2011) individuals with diabetes who have cancer have an increased risk for hospitalization. Diabetes is a risk factor for the development of infection and cardiac disease. Chemotherapy can also alter and have a negative effect on the immune and

cardiac systems. Individuals with diabetes and cancer undergoing chemotherapy are probably at higher risk for the development of complications when compared to cancer patients without diabetes. Due to this increased risk for hospitalization, it is important for healthcare providers to understand the importance of managing both the cancer and the diabetes. Improved coordination of care between oncologist and diabetes care providers needs to be a priority.

Summary

From the data collected from the open-ended questions, it is evident that cancer and chemotherapy has an impact on diabetes self-management, with 24 out of the 29 patients at 8 weeks reporting some type of impact on their diabetes self-management after 8 weeks of chemotherapy. Specifically the impact of cancer related symptoms on performance of diabetes self-management behaviors and the treatment effects from the chemotherapy and steroids they were on causing elevated glycemic levels. Five individuals reported no impact on their diabetes self-management. It is unknown if these individuals had high or low levels of diabetes self-management at the beginning. It is possible that they did not perform routine self-management prior to starting chemotherapy, and or had poor glycemic control when they first started treatment for their cancer. The level of performance of self-management activities may not equate to improved or adequate glycemic control in this population. Further research is needed to determine the actual impact cancer treatment has on glycemic control in older adults with both diabetes and cancer.

Discussion of Results in Relation to Conceptual Framework

The conceptual framework for this study was based on the framework for heart failure self-management with family variables by Dunbar et al (2008). This frame work utilized a structure-process-outcome format. The framework for this study utilized the structure

components of individual, clinical and behavioral characteristics and the process component of diabetes self-management behaviors at baseline and 8 weeks. The results of this study did show that the individual characteristic of age had an influence and was related to self-management behaviors at baseline. Ethnicity may have an influence on diabetes self-management at 8 weeks, due to the fact that most individuals were from the same ethnicity, further studies would need to be done to determine the true nature of this relationship.

Clinical characteristics of years with diabetes, number of comorbidities and diabetes severity were all found to be either correlated with or predictive of self-management behaviors for diabetes at 8 weeks. Years with diabetes was correlated with self-management behaviors at baseline, was not found to be a significant predictor for baseline self-management behaviors. DSE was the only behavioral characteristic to be positively correlated with baseline and 8 weeks self-management behaviors, and predictive of baseline self-management.

This framework was specifically developed to look at heart failure self-management; this study shows that some of the same characteristics which influence self-management for heart failure also influence diabetes self-management. Based on the results of this study, components of individual, clinical and behavioral characteristics all play a role in the performance of diabetes self-management in individuals undergoing treatment for cancer. Due to the small sample size it is possible that not all relationships were detected. It is unclear if behavioral characteristics have an influence on the performance of self-management activities at 8 weeks. In addition the entire model was not tested in this study.

The framework as depicted in chapter two, also did not account for the influence cancer-self-management may have on the performance of diabetes self-management behaviors. This model needs to be changed in order to take into consideration the role cancer self-management

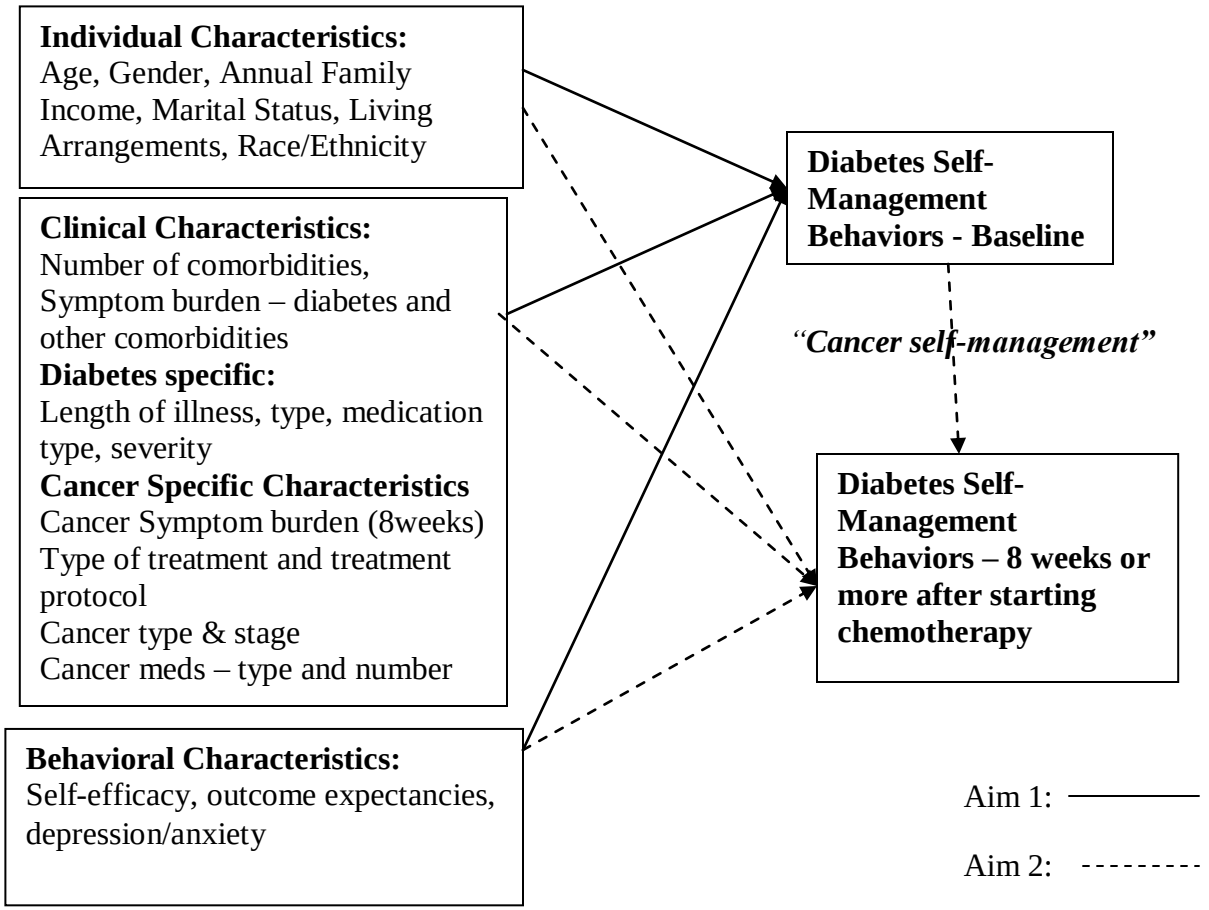

Figure 7: Revised framework depicting the influence of cancer self-management may have between baseline and 8 week diabetes self-management

activities may have in regards to the performance of diabetes self-management behaviors in adults undergoing chemotherapy for cancer. Figure 7 is a depiction of a revised model reflecting this possible change.

Study Limitations

This study is limited by the small sample size. The small sample limits the ability to generalize this to all patients with diabetes and cancer. Future studies need to improve on the recruitment of patients. One of the barriers for improved recruitment was the lack of having patient's consented onsite. The return rate for the surveys was adequate, more patients could have been captured by having someone consent them onsite. Phone calls could have been placed in order to remind them to complete the survey, or a phone survey could have been utilized in order to collect the data.

A second limitation of this study is that all date was self-reported. Self-report is a method frequently used in research. However, questions are open to individual interpretation by the respondent; the individual may not interpret the question correctly causing them to answer differently than intended. The baseline data for the study was collected by a self-administered written survey in which respondents returned and the 8 week follow up data was collected by a follow up phone survey. Potentially individuals may have answered differently on the written survey vs. the phone survey where they were actually responding to the study investigator. Future studies need to consider using one approach to data collection, to ensure consistency.

A third limitation is the lack of information regarding actual glycemic control individuals in the study had prior to starting chemo and during the data collection period. Many individuals reported problems with elevated glucose during this time. It is unclear if the increase in glycemic levels was new, or if individuals had prior issues with glycemic control and were more

aware of glycemic levels during this time. Future studies need to consider adding measures of glycemic control such as HgBA1c's, blood sugar diaries, and/or average daily glucose measurements.

Medical audit and clinical data in conjunction with self-report measures could be used to assess and confirm level of glycemic control, diabetes severity, years with diabetes, number and type of comorbidities, and the actual number of other medications, and the type of medications individuals are taking, as well as cancer specific clinical characteristics. This study collected information regarding the number of other medications individuals were taking, by knowing what types of medications individuals are on that may be impacting their glycemic control would be important to control for. Steroids are used in conjunction with the treatment of certain cancers, specifically lung cancer, as well as they are sometime used to help with symptoms associated with chemotherapy. The use of steroids is known to cause and elevation in blood glucose levels.

A fourth limitation of this study is that the same diabetes self-care measure was used at baseline and 8 weeks. It is possible that the baseline measure increased the participant's awareness regarding diabetes self-management and they improved their diabetes self-management behaviors while participating in the study.

A fifth limitation of this study was the short time period between the collection of baseline and final 8 week data. Eight weeks was selected to ensure that individuals had at least received 2 cycles of their chemotherapy. It is possible that individuals may experience a greater impact later on in treatment. It is also unknown if individuals would return back to pre-chemotherapy or baseline levels of diabetes self-management after they have adjusted to the cancer treatment regimen.

A sixth limitation of this study, was the instrument used to measure symptom severity. This instrument was originally designed to measure common symptoms of illness and was selected for its ability to measures symptoms associated with other comorbidities and chronic conditions along with cancer related symptoms. The tool measured severity by multiplying the frequency of the symptom by the level of interference the symptom caused in the individuals daily life. This is not a true measure for symptom severity; it is unknown how the patient would actually describe that symptom on a severity rating scale. Some individuals may have had a symptom for the same number of days, but experienced the symptom at different levels of intensity. Future research needs to utilize symptom tools that specifically measure the severity or intensity of the symptoms, and be specific to the disease being studied.

The final limitation to this study relates to the analysis and interpretation of the open ended questions. Thematic analysis was utilized to identify the themes; the data was only reviewed by one reviewer. In order to state these were the actual themes, and there weren't other possible themes, the data should have been reviewed by at least one other reviewer. The themes compared and discussed, and then agreement reached between the two reviewers on what the actual themes were. Member checking could also have been utilized to ensure that the themes were interpreted correctly. Member checking involves taking the identified and defined themes back to the respondents for confirmation and agreement. In addition the questions utilized where worded in a way that members would focus on issues with their diabetes management. Due to this, members did not discuss other issues or feeling about their cancer or cancer treatment and it is possible that other factors could have been identified that may have been a potential barrier to the self-management of diabetes with these expanded questions.

Implications for Nursing Practice

The combined results of the quantitative analysis and the open ended questions indicated clinical issues that nurses and other health care providers need to be aware of in this population. Issues include: problems with glycemic control; barriers to being able to adhere to diet and exercise regimens; and the fact that both patients and healthcare providers may not find diabetes management to be a priority while undergoing chemotherapy. In addition oncologist and oncology nurses may not understand diabetes management, and what self-management behaviors patients with diabetes should perform on a daily basis.

Oncology nurses need to be aware of the problems individuals with diabetes and cancer may encounter, and encourage patients who are undergoing chemotherapy to continue to manage their diabetes. Nurses and other health care providers who care for individuals with both diabetes and cancer need to be made aware of the issues this population of patient's encounters. Through conference presentations, in-services and publications the awareness of these individuals could possibly be increased. The level of knowledge oncology nurses have regarding managing diabetes in the oncology patient needs to be assessed. Based on this knowledge, tailored inservices and training sessions can be developed to meet the specific needs of these healthcare providers.

Interventions need to be developed in order to assist oncology nurses in regards to helping patients manage their diabetes while they are undergoing chemotherapy. The oncology nurse will have frequent contact with these individuals while they are receiving treatment. Depending on the type of cancer, chemotherapy treatments can occur anywhere from weekly to monthly. The oncology nurse can frequently assess if individuals are having issues with their

diabetes management, and refer them to the appropriate provider if necessary for further intervention.

Implications for nursing and other health care providers include both health care provider directed interventions and patient directed interventions. In order to improve health related outcomes in this population oncology nurses, oncologists and primary diabetes providers need to be aware of the issues; knowledgeable about possible interventions that could be effective in improving outcomes in this population; and work together to provide coordinated care that focuses on managing both the diabetes and cancer simultaneously. Nursing interventions could include: 1) educational pamphlets that can be given to patients explaining the importance of continuing to manage their diabetes; 2) development of protocols for how to manage blood sugars, which may include utilizing insulin to scale based on blood sugar readings; 3) information regarding how best to manage their diet when they are dealing with side-effects from the chemotherapy; 4) strategies for exercising while undergoing chemotherapy and 5) coordinating care with a diabetic nurse practitioner or educator, and/or the patients primary care provider. Care guidelines for oncologist, oncology nurses, endocrinologist, advance practice nurses, diabetes educators and primary care providers who are caring for individuals with cancer and diabetes need to be developed and disseminated to ensure that these patients with diabetes and cancer can achieve the best possible diabetes and cancer outcomes.

Implications for Research

This study highlights the need for further research which investigates the relationship between diabetes and cancer in regards to the impact cancer and its treatment has on diabetes outcomes, as well as the impact diabetes has on cancer related outcomes. Research needs to occur in several areas: outcomes, intervention development and translation. Once we understand

the relationship between cancer and diabetes and vice versa, and have tested and proven interventions which improve outcomes, we may be able to transfer these to other individuals with competing or discordant conditions, such as congestive heart failure (CHF) and cancer, or diabetes and CHF. The following paragraphs will explore further each of these areas.

In the area of outcomes, further understanding of the relationship between glycemic control and its relationship to cancer related outcomes such as survivorship, mortality and morbidity, as well as health related outcomes of physical function, health care utilization and symptom burden need to be developed. Research looking at the relationship of self-management and glycemic control in individuals undergoing treatment for cancer, and health related outcomes needs to be developed. It is unclear if the impact on self-management is part of the reason for poor glycemic control and poorer cancer related outcomes in individuals with diabetes and cancer. In addition does diabetes and level of glycemic control alter the effectiveness of the chemotherapy and other treatments for cancer? Do patients with diabetes need a different treatment protocol to treat their cancer than individuals who do not have diabetes. We need to conduct studies which will improve our understanding of the underlying pathophysiological mechanisms which occur in individuals with diabetes and cancer, in order to develop interventions that will improve survivorship and overall quality of life for individuals with diabetes and cancer.

Interventions need to be developed which focus on improving health related quality of life, diabetes self-management, glycemic control, and the dual management of diabetes and cancer. Specific treatment protocols need to be developed and tested which will provide guidance to oncology nurses, oncologists and primary care providers in order to improve

glycemic control, decrease complications, treatment side effects and adverse reactions, hospitalizations, and improve survivorship in this population.

Once these interventions have been developed and tested, they then need to be translated to the clinical practice arena. Research will need to be done that allows for the testing of interventions that have been shown to have an impact on health related outcomes and glycemic control in individuals with cancer and diabetes, to other populations. Clinical research needs to be done in order to develop evidence based protocols which improve glycemic control, treatment side effects and potential adverse reactions in individuals with diabetes while undergoing chemotherapy for cancer. A randomized control trial which compares various treatment protocols for managing diabetes needs to be developed. These trials should look at multiple outcomes, in order to develop a treatment guideline for individuals with diabetes and cancer. Outcomes should include glycemic control, complication rates such as infections and hospitalizations as well as quality of life indicators. In addition the information gained from research needs to be translated to the individual patients through the development of guidelines which can assist patients in the self-management of their diabetes while undergoing chemotherapy.

Implications for Policy

This study highlights the need for the development of policies and protocols which can improve outcomes for individuals with multimorbidities. Currently diabetes and cancer are managed separately, as this study noted; providers may prioritize the management of one disorder over the other. One of the goals of cancer care is long term survivorship, and improved quality of life for individuals with cancer. Diabetes care strives for prevention or delay of potential complications, optimal glycemic control, as well as improved quality of life. Quality

indicators for diabetes management in individuals with cancer who are undergoing treatment need to be developed. These indicators should include acceptable glycemic levels, measured by HgBA1c or average daily glucose levels, complication rates for infection occurrence and hospitalizations related to both conditions, diabetes and cancer, and the response to treatment.

Policies and protocols need to be developed which allow for better coordinated care for individuals with diabetes and cancer. Currently we don't have guidelines which address how to best care for individuals with cancer and diabetes. As stated in the research implications section, specific interventions and protocols need to be developed and tested.

In order to be successful in providing higher quality of care to this population, stakeholders such as payers and policy makers need to be considered. Our protocols and guidelines need to ensure the highest quality of care at the lowest cost. Payers and policy makers need to see the benefit of supporting quality indicators which could be part of a pay for performance system in individuals with diabetes and cancer. Does improved care coordination actually translate to less cost overall. The goal would be to demonstrate improved care coordination can decrease complications, hospitalizations, and possibly the loss of productive days in individuals with cancer and diabetes, which could translate to lower cost, better outcomes and improved quality of life.

One of the aims of the Patient Protection and Affordable Care Act (PPACA) of 2010 was to improve care coordination for individuals with multiple chronic conditions, such as diabetes and cancer (Justice, 2010). The PPACA establishes demonstration projects within the Medicare program to test models for delivery of healthcare services and payment reform which include Medical Homes and Accountable Care Organizations (ACO) (Justice, 2010). These medical homes and ACO's could be mechanisms to evaluate and support care coordination services for

individuals with diabetes and cancer, to see if utilization of services, hospitalization rates, complications such as infections, cardiac events, and health care costs decrease, and outcomes improve.

Conclusion/Summary

The primary purpose of this study was to identify factors which may influence diabetes self-management in adults 50 and older who were undergoing chemotherapy for a solid tumor cancer. The secondary purpose was to identify specific issues or challenges individuals with diabetes and cancer faced in regards to caring for their diabetes while undergoing chemotherapy. The results indicated that age and level of self-efficacy were predictors of baseline self-management in this population. After at least 8 weeks of chemotherapy, years with diabetes, number of comorbidities, and baseline diabetes self-management were predictors of better self-management when compared to individuals with fewer years, fewer comorbidities and lower baseline self-management.

A sub-analysis was performed in order to identify if there was a change between baseline self-management and diabetes self-management after at least 8 weeks of chemotherapy. Individuals in this study did have lower self-management scores at 8 weeks, indicating that chemotherapy and or its side-effects had an impact on the management of their diabetes. This impact was directly seen on the self-management areas of diet and exercise.

Through qualitative data, individuals identified issues with diet and exercise, due to impact of symptoms such as nausea, vomiting, loss of appetite and fatigue. This data also revealed that patient may not prioritize caring for their diabetes when faced with cancer and undergoing treatment. Glycemic control during cancer treatment was an issue for many of the

participants, with most reporting problems with hyperglycemia, and difficulty in keeping their blood glucoses with in a normal range.

Prior to this study, studies that specifically addressed the impact of a new discordant condition (cancer) on an existing chronic disease (diabetes) were very limited or scarce in the literature. Studies specifically looking at the impact on self-management were not found. This study contributes to the science by adding knowledge regarding how one condition can have a negative impact on another, and increasing the need for better care coordination and management. Treatment protocols need to be developed which can provide for improved care for patients with competing chronic conditions in order to improve health related quality of life outcomes. Nurses can play an essential role in the development and implementation of these outcomes and can take the lead in regards to research and development of interventions that can influence nurse-sensitive outcomes, such as symptoms and self-care.

APPENDICES

APPENDIX A

Baseline Survey Instrument

Diabetes and Cancer Self-management Study Survey Tool: (Baseline)

Thank-you for your willingness to participate in this study, this survey will ask you several questions about your diabetes, cancer, symptoms you may be having, and what you do to care for your diabetes. The survey should take you 45 – 60 minutes to complete. Once you have completed the survey, place in the provided envelope along with your signed consent form and return to the study investigator. Once again, thank you for taking part in this study, once the study investigator receives your completed survey and consent; she will be contacting you to set up the follow up phone interview.

The following are basic questions about you, please answer each question:

1. Gender: (circle one)
   a. Male
   b. Female

2. What is your date of birth: _ _ / _ _ / _ _ _ _ (mm/dd/yyyy) (write in date)

3. What is your highest level of education completed? (circle one)
   a. No formal education or completed grade school
   b. Completed some high school
   c. Completed high school
   d. Completed some college or technical training
   e. Completed college

4. What is race do you consider yourself? (circle one)
   a. Caucasian/White
   b. African American/Black
   c. Mexican American/Hispanic/Chicano
   d. Native American/ Alaskan
   e. Other: (specify):_____

5. What is your ethnic background: (circle one)
   a. Hispanic or Latino
   b. Not Hispanic or Latino

6. What is your current marital status: (circle one)
   a. Never Married
   b. Married
   c. Divorced/Separated
   d. Widowed
   e. Living Together

7. What is your current living arrangement: (circle one)

a. Live alone
b. Live with spouse/significant other
c. Live with a family member other than your spouse or significant other
d. Live with a non-family member

8. How many individuals live in your home:_____ (Write in number)

9. What was your combined household income last year? (circle one)
   a. Less than 49,999
   b. $50,000 – 99,999
   c. $100,000 – 149, 999
   d. $150,000 – 199,999
   e. $200,000 or above

The following questions are specific about your Diabetes:

1. What type of Diabetes do you have: (circle one)
   a. Type I (non-adult onset, Juvenile Diabetes)
   b. Type II (Adult onset)

2. What types of medications do you take for your Diabetes: (circle one)
   a. Insulin
   b. Oral medications to lower your blood sugar
   c. Both Insulin and oral medications

3. How long have you had Diabetes: _____(write in number of years)

4. How many medications do you take total for your diabetes: _____(write in number)

5. How many other medications (**those for health conditions other than your diabetes or cancer**) do you take:_____(write in number)

The following questions are about conditions which are possibly related to your diabetes, please answer YES or NO to each of the following items: (Based on the Diabetes Complications Index)

		Yes	**No**
1.	Has a doctor ever told you that you have a blockage in the blood flow to your heart? Such blockage can lead to chest pain; also called angina.		
2.	In the past 6 months have you had chest pain or pressure?		
	If yes, was the chest pain or pressure brought on by physical activity or stress?		

If yes, Was the chest pain or pressure relieved by rest or nitroglycerine?		
3. Has a doctor ever told you that you have had a TIA? This is also called "Transient Ischemic Attack" or "warning stroke" or have you ever developed sudden, stroke like symptoms, for example, weakness on one side of your body, difficulty speaking, drooping of one side of our mouth, drooling or trouble seeing, which completely returned to normal within a day?		
4. Has a doctor ever told you that you have blockages in the blood vessels, arteries to your legs, also called peripheral vascular disease or during the past 6 months, have you had leg cramps or pain in your calf while walking, which was relieved by rest?		
5. During the past 6 months have you had no feeling or numbness in your feet?		
6. During the past 4 weeks, have you had loss or bowel control or diarrhea while sleeping?		
7. During the past 6 months have you had ulcers on your toes, feet or lower legs?		
8. Have you ever had gangrene on any of your toes?		
9. Have you ever had any part of your toes or feet amputated because of diabetes?		
10. Has a doctor ever told you that you have retinopathy or diabetic eye disease, or do you now have cataracts?		

The following questions are about health conditions you currently have other than your diabetes or cancer, please answer YES or NO to each of the following items: (Based on the Katz Comorbidity Index)

	Yes	**No**
1. Has a doctor ever told you that you have high blood pressure or Hypertension?		
2. Has a doctor ever told you that you have Asthma?		
3. Has a doctor ever told you that you have a chronic lung condition other than Asthma (such as COPD or Emphysema) ?		
4. Has a doctor ever told you that you have congestive heart failure?		
5. Has a doctor ever told you that you had a heart attack, coronary heart disease, angina or other heart problems?		
6. Has a doctor ever told you that you had a stroke?		
7. Has a doctor every told you that you have a neurological condition such as Parkinson's, seizure disorder or multiple sclerosis?		

	Yes	No
8. Has a doctor every told you that you have arthritis or rheumatism?		
9. Has a doctor ever told you that you have a emotional, nervous or psychiatric problem?		
10. Do you have any other health conditions no already mentioned?		
IF yes: what are they: (please write in)		

The following questions are about symptoms (based on the Symptoms of Illness Checklist), **you may be experiencing related to your diabetes or other health problems:** Next to each symptom, there are two columns, titled **"Number of days symptom was present"** and **"Interference with "DAILY ACTIVITIES"**. For each symptom, please place an **X** in the box which reflects the number of days you had the symptom over the past month and place an **X** in the box which reflects how much the symptom interfered with your daily activities.

	Number of days symptom was present during month					Interference with Daily activities			
SYMPTOM	**Did Not Have**	**1 – 3 days**	**4 – 7 days**	**8 – 14 days**	**15 – 30 days**	**Did not Interfere**	**Slightly Interfered**	**Considerably Interfered**	**Severely Interfered**
Sore Throat									
High Blood Pressure									
Ear Problems (Ear ache or pain, ringing or buzzing in ears etc)									
Muscle aches or pain not due to strenuous exercise or joints									
Joint (not muscle) problems (stiffness, pain, swelling etc)									
Cough due to illness									
Respiratory problems other than cough (wheezing, trouble breathing, shortness of breath, etc)									

	Number of days symptom was present during month					Interference with Daily activities			
SYMPTOM	**Did Not Have**	**1 – 3 days**	**4 – 7 days**	**8 – 14 days**	**15 – 30 days**	**Did not Interfere**	**Slightly Interfered**	**Considerably Interfered**	**Severely Interfered**
Back and neck problems (back aches, backpain, etc)									
Sleeping Problems (trouble falling asleep, insomnia, etc.)									
Abdominal pain, (due to ulcers, acid indigestions, appendicitis etc)									
Feeling exhausted or fatigued									
Blood in feces (stool)									
Skin rash anywhere on the body									
Urinary problems (painful urination, blood in urine, etc)									
Lightheaded, faint, dizzy									
Chest pain									
Constipation									
Diarrhea									
Eye problems (redness, impaired, discharge or blurry vision, etc)									
Dental Problems (bleeding or discomfort in gums, teeth or mouth, canker sores, etc)									
Sinus Problems									
Nasal Problems (runny nose, congested nasal passages, etc)									
Nausea (stomach sickness, inclination to vomit, etc)									
Headaches (migraine or other)									
Fever									
Swollen ankles or feet									
Muscle twitching									
Cold sores									

	Number of days symptom was present during month					Interference with Daily activities			
SYMPTOM	**Did Not Have**	**1 – 3 days**	**4 – 7 days**	**8 – 14 days**	**15 – 30 days**	**Did not Interfere**	**Slightly Interfered**	**Considerably Interfered**	**Severely Interfered**
Numbness/tingling in hands or feet									
Menstrual Problems									
Change in appetite (loss of appetite, overeating, etc)									
Swollen glands in neck									

The following questions are about your Cancer and Cancer Care:

1. What type of Cancer do you have? (circle all that apply)
   a. Breast
   b. Colon
   c. Lung
   d. Bladder
   e. Liver
   f. Gynecological (other than ovarian)
   g. Gastrointestinal (other than Liver or pancreas)
   h. Pancreas
   i. Lymphoma
   j. Prostate
   k. Ovarian
   l. Other: _____list type

2. What stage is your cancer? (circle one)
   a. Early
   b. Late

3. Have you had cancer before? (circle one)
   a. Yes
   b. No

4. Do you have metastasis or your cancer is in more than one place in your body? (circle one)
   a. Yes

b. No

5. What type of treatment are you receiving for your cancer? (circle all that apply)
   a. Chemotherapy (intravenous)
   b. Radiation
   c. Oral Chemotherapy
   d. Other: _____(write in)

6. When did you or will you start your chemotherapy treatments: _____(write in date of first treatment)

If you are RECEIVING INTRAVENOUS CHEMOTHERAPY TREATMENTS (if not, skip question 6)

7. How often do you receive your intravenous treatments? (circle one)
   a. Once a month
   b. Twice monthly
   c. Weekly
   d. Twice weekly
   e. Other_____

If you are RECEIVING RADIATION TREATMENTS (if not, skip question 7)

8. How often do you receive your radiation treatments? (circle one)
   a. Once a month
   b. Twice monthly
   c. Weekly
   d. Twice weekly
   e. Daily
   f. Other_____

If you are TAKING an ORAL CHEMOTHERAPY AGENT (if not, skip question 8)

9. How often do you take your oral chemotherapy pill: (circle one)
   a. Weekly
   b. Every other week
   c. Twice a week
   d. Every other day
   e. Daily
   f. Other:_____

10. Do you take any medications for your cancer or cancer related symptoms:
    a. yes
    b. no

If YES: How many different medications do you take: _____(please write in number)

The following questions ask about how much you believe you can perform certain activities to manage your diabetes. These are measured on a 1 – 5 scale, with 1 meaning 'No, I am sure I cannot', and 5 being 'Yes, I am sure I can'. Select a number from 1 – 5 which best reflects your ability to perform each of the activities. (Based on the Confidence in Diabetes Self-care Scale)

1. I believe I can plan my meals and snacks according to dietary guidelines.	1	2	3	4	5
2. I believe I can check my blood glucose at least two times a day	1	2	3	4	5
3. I believe I can detect high levels of blood glucose in time to correct	1	2	3	4	5
4. I believe I can detect low levels of blood glucose in time to correct	1	2	3	4	5
5. I believe I can treat a high blood glucose correctly	1	2	3	4	5
6. I believe I can treat a low blood glucose correctly	1	2	3	4	5
7. I believe I can keep daily records of my blood glucose	1	2	3	4	5
8. I believe I can decide when its necessary to contact my doctor or diabetes educator	1	2	3	4	5
9. I believe I can ask my doctor questions about my treatment plan	1	2	3	4	5
10. I believe I can keep my blood glucose in the normal range when under stress	1	2	3	4	5
11. I believe I can check my feet for sores or blisters every day	1	2	3	4	5
12. I believe I can inform colleagues/others of my diabetes if needed	1	2	3	4	5
13. I believe I can ask friends or relatives to help with my diabetes	1	2	3	4	5
14. I believe I can keep my medical appointments	1	2	3	4	5
15. I believe I can exercise two or three times weekly	1	2	3	4	5
16. I believe I can figure out what foods to eat when dining out	1	2	3	4	5
17. I believe I can read and hear about diabetes complications without getting discouraged	1	2	3	4	5
18. I believe I can take my medications as prescribed	1	2	3	4	5

Please answer the following questions if you are on Insulin (if not skip)					
19. I believe I can perform the prescribed number of daily insulin injections	1	2	3	4	5
20. I believe I can adjust my insulin for exercise, traveling or celebrations	1	2	3	4	5
21. I believe I can adjust my insulin when I am sick	1	2	3	4	5

The following questions are about how much you think performing specific activities is important to controlling your diabetes. Rate your answers based on a scale of 1 to 10, with 1 meaning 'Not at all important', and 10 meaning 'Very important'. (Based on the Outcomes Expectancy subscale of the Multidimensional diabetes Questionnaire)

1. To what extent do you think that following your diet is important to controlling your diabetes?	1 2 3 4 5 6 7 8 9 10
2. To what extent do you think that taking your medication as recommended (pills, Insulin) is important for controlling your diabetes?	1 2 3 4 5 6 7 8 9 10
3. To what extent do you think that exercise is important for controlling your diabetes?	1 2 3 4 5 6 7 8 9 10
4. To what extent do you think that measuring your blood sugar is important for controlling your diabetes?	1 2 3 4 5 6 7 8 9 10
5. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for controlling your diabetes?	1 2 3 4 5 6 7 8 9 10
6. To what extent do you think following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for delaying and/or preventing long term diabetes complications (problems related to eyes, kidneys, heart or feet).	1 2 3 4 5 6 7 8 9 10

The following questions are about your mood and feelings. Read every sentence, then circle the answer that best describes how you have been feeling during the LAST WEEK. You do not have to think too much to answer, your first thought is the most important.

I feel tense or "wound up"	Most of the time A lot of the time From time to time (occasionally) Not at all
I still enjoy the things I used to enjoy:	Definitely as much

	Not quite as much Only a little Hardly at all
I get a sort of frightened feeling as if something awful is about to happen:	Very definitely and quite badly Yes, but not too badly A little, but it doesn't worry me Not at all
I can laugh and see the funny side of things:	As much as I always could Not quite so much now Definitely not so much now Not at all
Worrying thoughts go through my mind:	A great deal of the time A lot of the time From time to time, but not often Only occasionally
I feel cheerful:	Not at all Not often Sometime Most of the time
I can sit at ease and feel relaxed:	Definitely Usually Not often Not at all
I feel as if I am slowed down:	Nearly all the time Very often Sometimes Not at all
I get a sort of frightened feeling like "butterflies" in the stomach:	Not at all Occasionally Quite often Very often
I have lost interest in my appearance:	Definitely I don't take as much care as I should I may not take quite as much care I take just as much care
I feel restless as I have to be on the move:	Very much indeed Quite a lot Not very much Not at all
I look forward with enjoyment to things:	As much as I ever did

	Rather less than I used to Definitely less than I used to Hardly at all
I get sudden feelings of panic:	Very often indeed Quite often Not very often Not at all
I can enjoy a good book or radio/TV program:	Often Sometimes Not often Very seldom

The following questions are about the activities you do, base on what you have been advised to do to manage your diabetes. Select a number from 1 to 5 that best reflects: How have you followed your diabetes treatment plan in the past 2 weeks? (Based on the Self-care Inventory-revised).

	Never	**Rarely**	**Sometimes**	**Usually**	**Always**	
1. Check blood glucose with monitor	1	2	3	4	5	
2. Record blood glucose results	1	2	3	4	5	
3. If type 1: Check ketones when glucose is high	1	2	3	4	5	Have type 2 diabetes
4. Take correct dose of diabetes pills or insulin	1	2	3	4	5	
5. Take diabetes pills or insulin at the right time	1	2	3	4	5	
6. Eat the correct food portions	1	2	3	4	5	
7. Eat	1	2	3	4	5	

	Never	Rarely	Sometimes	Usually	Always	
meals/snacks on time						
8. Keep food records	1	2	3	4	5	
9. Read food labels	1	2	3	4	5	
10. Treat low blood glucose with just the recommended amount of carbohydrate	1	2	3	4	5	Never had low blood glucose
11. Carry quick acting sugar to treat low blood glucose	1	2	3	4	5	
12. Come in for clinic appointments	1	2	3	4	5	Did not have appointment
13. Wear a Medic Alert ID	1	2	3	4	5	
14. Exercise	1	2	3	4	5	
15. If on insulin: adjust insulin dosage based on glucose values, food and exercise	1	2	3	4	5	Not on Insulin

Thank-you for completing the survey, you will be receiving a call from the study investigator after she receives the completed survey and consent form in the mail, this should be within 1 – 2 weeks after the survey has been mailed.

APPENDIX B

Eight Week Survey Instrument

Eight Week Telephone Survey: Inform the participants that their answers are being audio taped.

The following questions are about symptoms (based on the Symptoms of Illness Checklist), **you may be experiencing:** Next to each symptom, there are two columns, titled **"Number of days symptom was present"** and **"Interference with "DAILY ACTIVITIES"**. For each symptom, please place an **X** in the box which reflects the number of days you had the symptom over the past month and place an **X** in the box which reflects how much the symptom interfered with your daily activities.

	Number of days symptom was present during month					**Interference with Daily activities**			
SYMPTOM	**Did Not Have**	**1 – 3 days**	**4 – 7 days**	**8 – 14 days**	**15 – 30 days**	**Did not Interfere**	**Slightly Interfered**	**Considerably Interfered**	**Severely Interfered**
Sore Throat									
High Blood Pressure									
Ear Problems (Ear ache or pain, ringing or buzzing in ears etc)									
Muscle aches or pain not due to strenuous exercise or joints									
Joint (not muscle) problems (stiffness, pain, swelling etc)									
Cough due to illness									
Respiratory problems other than cough (wheezing, trouble breathing, shortness of breath, etc)									
Back and neck problems (back aches, backpain, etc)									
Sleeping Problems (trouble falling asleep, insomnia, etc.)									
Abdominal pain, (due to ulcers, acid indigestions, appendicitis etc)									
Feeling exhausted or fatigued									
Blood in feces (stool)									
Skin rash anywhere on the body									
Urinary problems (painful urination, blood in urine, etc)									
Lightheaded, faint, dizzy									
Chest pain									

	Number of days symptom was present during month					Interference with Daily activities			
SYMPTOM	**Did Not Have**	**1 – 3 days**	**4 – 7 days**	**8 – 14 days**	**15 – 30 days**	**Did not Interfere**	**Slightly Interfered**	**Considerably Interfered**	**Severely Interfered**
Constipation									
Diarrhea									
Eye problems (redness, impaired, discharge or blurry vision, etc)									
Dental Problems (bleeding or discomfort in gums, teeth or mouth, canker sores, etc)									
Sinus Problems									
Nasal Problems (runny nose, congested nasal passages, etc)									
Nausea (stomach sickness, inclination to vomit, etc)									
Headaches (migraine or other)									
Fever									
Swollen ankles or feet									
Muscle twitching									
Cold sores									
Numbness/tingling in hands or feet									
Menstrual Problems									
Change in appetite (loss of appetite, overeating, etc)									
Swollen glands in neck									

The following questions are about the activities you do, base on what you have been advised to do to manage your diabetes. Select a number from 1 to 5 that best reflects: How have you followed your diabetes treatment plan in the past 2 weeks? (Based on the Self-care Inventory-revised).

	Never	**Rarely**	**Sometimes**	**Usually**	**Always**	
1. Check blood glucose with monitor	1	2	3	4	5	
2. Record blood						

glucose results	1	2	3	4	5	
3. If type 1: Check ketones when glucose is high	1	2	3	4	5	Have type 2 diabetes
4. Take correct dose of diabetes pills or insulin	1	2	3	4	5	
5. Take diabetes pills or insulin at the right time	1	2	3	4	5	
6. Eat the correct food portions	1	2	3	4	5	
7. Eat meals/snacks on time	1	2	3	4	5	
8. Keep food records	1	2	3	4	5	
9. Read food labels	1	2	3	4	5	
10. Treat low blood glucose with just the recommended amount of carbohydrate	1	2	3	4	5	Never had low blood glucose
11. Carry quick acting sugar to treat low blood glucose	1	2	3	4	5	
12. Come in for clinic appointments	1	2	3	4	5	Did not have appointment
13. Wear a Medic Alert ID	1	2	3	4	5	
14. Exercise	1	2	3	4	5	
15. If on insulin: adjust insulin dosage based on glucose	1	2	3	4	5	Not on Insulin

values, food and exercise						

The following items ask about how much your cancer and/or its treatment interferes with different aspects of your diabetes self-management. Please **circle the one number** that best describes your current status. Rate each item based on a 1 – 7 scale with 1 being equal to not very much to 7 being equal to very much.

How much does your cancer and its treatment interfere with:

1. The things you eat and drink to manage your diabetes:
   (not very much) 1 2 3 4 5 6 7 (very much)

2. Exercising:
   (not very much) 1 2 3 4 5 6 7 (very much)

3. (Controlling, Managing, Monitoring??? – not sure of the best word to use here) your blood glucose levels:
   (not very much) 1 2 3 4 5 6 7 (very much)

4. Taking your diabetes medications at the right time:
   (not very much) 1 2 3 4 5 6 7 (very much)

5. Performing self-management activities and caring for your diabetes in general:
   (not very much) 1 2 3 4 5 6 7 (very much)

Please answer the following questions:

Based on your experiences over the past 8 weeks, what do you think have been some of the challenges or issues you have had to face in regards to managing your diabetes?

In general describe how your diabetes has been affected or impacted since you started undergoing chemotherapy for your cancer?

APPPENDIX C

Study Consent Form

Research Participant Information and Consent Form

You are being asked to participate in a research project. Researchers are required to provide a consent form to inform you about the study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Study Title: Older Adults with Diabetes and Cancer: Impact on Diabetes Self-Management

Researcher and Title: Denise Soltow, MSN, FNP-BC, Doctoral Candidate
Barbara Given, RN, PhD, FAAN, Associate Dean for Research
Department and Institution: College of Nursing, Michigan State University
Address and Contact Information: Mail: Michigan State University, College of Nursing -PhD Program, 417B West Fee Hall, E. Lansing, MI 48824. Phone: (toll free) 1-877-595-6426.

1. PURPOSE OF RESEARCH:

You are being asked to participate in a research study to investigate how diabetes self-management may be impacted or changed in older adults who are undergoing treatment for cancer. You have been selected as a possible participant in this study because you have a prior history of diabetes and you are being treated with either insulin or an oral medication. You have also been, recently diagnosed with cancer and are eligible to receive either intravenous or oral chemotherapy to treat your cancer or are currently receiving chemotherapy. From this study, the investigators hope to better understand issues or problems associated with diabetes self-management while being treated for cancer, so that new treatments which may improve the care process for individuals with diabetes and cancer. In the entire study, a total of 60 individuals are being asked to participate. Your participation in this study will take about 45 - 60 minutes to complete the initial written survey and 20 minutes for a follow up survey to be completed over the phone 8 weeks later.

2. WHAT YOU WILL DO:

For this study you will be required to complete an initial written questionnaire and return in the provided self-addressed stamped envelope. After the study investigator has received your initial questionnaire she will contact you by telephone at the number you provided in order to confirm your willingness to participate in the study and to set up an approximate time for your follow up telephone survey 8 weeks later. The follow up survey will take approximately 20 minutes. Once the follow up survey is completed you will have no further requirements for this study.

Since, every individual responds differently to their cancer treatment, if due to side effects from the treatment you are unable to complete the follow up survey at the prior established time, the study investigator will ask if you are willing to set up another time within the next week in order to complete the survey.

If you would like to receive a final summary of the results of this study, please indicate to the study investigator at the initial contact, and after the study is completed, a final summary will

be mailed to you. Your participation in this study is entirely voluntary and compensation for your participation will not be provided.

4. POTENTIAL BENEFITS:

You will not directly benefit from your participation in this study. However, your participation in this study may contribute to the understanding of how cancer and its treatment may impact diabetes management and care for older adults. This understanding may lead to new interventions which could help to improve health related outcomes for individuals with diabetes and cancer in the future.

5. POTENTIAL RISKS:

As with any research study, there may be additional risks to the participant that are currently unforeseeable. Potentially individuals participating in this study may develop some distress due to the questions regarding the management of their diabetes. All individuals approach how they manage their diabetes differently, and if for some reason you develop concerns, you will be advised to contact your diabetes care provider in order to discuss. It is not anticipated that any of the questions would produce more than a minimal level of distress. If for some reason, you develop a high level of distress, you will be given resources for help. Contact numbers for local crisis centers are included in the packet you received when you were asked to participate in the study.

6. PRIVACY AND CONFIDENTIALITY:

The data for this project are being collected confidentially. Only the researcher will be able to link data to you. Your name and contact information will be kept separate from your completed surveys. Your surveys will only have an ID number which the researcher can use to link to your contact information. Once the study is completed, your contact information will be destroyed.

The phone interview, which will occur at 8 weeks after you have enrolled in this study, will be audio taped. These tapes will not have any identifying data other than your study ID on them. These tapes will be kept in a locked file in which the researcher will be the only person who has access. The researcher will conduct the phone interview in a private setting, in order to keep the conversation private.

Information about you will be kept confidential to the maximum extent allowable by law unless there is a danger to yourself or others. Only the principle investigators and the Michigan State University Institutional Review Board (IRB) will have access to records which have identifying data. All records will be kept for a minimum of 3 years, and will be stored in a lock file in the College of Nursing Research Center.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

7. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

Participation in this research project is completely voluntary. You have the right to say no. You may change your mind at any time and withdraw. If you decide to withdraw, the care you receive for your diabetes and/or your cancer **will not** be affected.

You may choose not to answer specific questions or to stop participating at any time. Choosing not to participate or withdrawing from this study will not make any difference in the quality of any treatment you may receive or benefits to which you are otherwise entitled.

8. COSTS AND COMPENSATION FOR BEING IN THE STUDY:

It is possible you may incur a cost if you use a cell phone for your primary phone. For, you may incur charges for minutes used if you go over the minutes included in your cell phone plan. If you use a phone other than a cell phone, there are no potential costs to you for participating in this study. You will not receive money or any other form of compensation for participating in this study.

9. THE RIGHT TO GET HELP IF INJURED:

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact study investigator Denise Soltow at 1-877-595-6426 with any questions or to report an injury.

10. CONTACT INFORMATION FOR QUESTIONS AND CONCERNS

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher Denise M. Soltow or Barbara Given by mail at Michigan State University, College of Nursing, PhD Program, 417B West Fee Hall, E. Lansing, MI 48824. Phone: 1-877-595-6426.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 207 Olds Hall, MSU, East Lansing, MI 48824.

11. DOCUMENTATION OF INFORMED CONSENT

Your signature below means that you voluntarily agree to participate in this research study. There are two copies of this consent form in your packet, one for you to sign and return if you wish to participate in this study, and one for you to keep for your records.

Signature_____Date_____

Please complete the following contact information:

Name: (printed)_____

Phone: __ __ __ - __ __ __ - __ __ __ __
(Area code)

Best time to Call:

Day of week: (circle all that apply) Sunday Monday Tuesday Wednesday Thursday Friday Saturday

Time of Day: (circle all that apply) Morning Afternoon Evening

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